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MSc in Nutrition and Dietetics

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Keeping up with technology – The development of a tablet-based multimedia education programme for women with a history of gestational diabetes: a formative evaluation

Helen Jacobs

Student number: 1102133

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ABSTRACT

BACKGROUND

A history of gestational diabetes significantly increases the risk of progression to type 2 diabetes (T2DM). Lifestyle intervention is an effective technique for delaying or preventing the onset of T2DM in this population and represents a unique opportunity for the primary prevention of type 2 diabetes. Following gestational diabetes, women face significant barriers to engaging in education and achieving health behaviour change. A multimedia patient education programme could overcome the barriers and be an effective method of reaching this population.

OBJECTIVE

The aim of the programme was to support women with a recent history of gestational diabetes to make lifestyle changes with the view to reduce the risk of type 2 diabetes in the future. This stage of the project aimed to evaluate the relevance, usability, content and appearance of the programme and also to identify any issues with the programme prior to proceeding to clinical trial.

METHODS

The multimedia education programme was developed using a five stage system development method: identification of user requirements, system design, system development, system evaluation and system application. Experts and patient representatives assessed the relevance, usability, content and appearance through a formative evaluation.

RESULTS

The multimedia education programme ‘Keeping Healthy after Gestational Diabetes’ contained seven modules: introduction, health, diet, lifestyle, baby health, living post GDM and warning signs. The formative evaluation by 22 experts and 20 patient representatives has provided valuable direction for the on-going development of the programme and suggest that the programme is relevant, easy to use, interesting and visually appealing.

CONCLUSION

Findings suggest that users found the programme relevant, easy to use, interesting and visually appealing; suggesting that this may be a feasible and acceptable mode of education.

DECLARATION OF ORIGINAL WORK

I hereby declare that work contained herewith is original and is entirely my own work (unless indicated otherwise). It has not been previously submitted in support of a Degree, qualification or other course.

Signed _____ Date _____

CONTENTS

LIST OF FIGURES

LIST OF TABLES

LIST OF ABBREVIATIONS

BMI – Body Mass Index

DoH – Department of Health

DPP – Diabetes Prevention Programme

FBG – Fasting blood glucose

GDM – Gestational diabetes

HbA1C – Glycated Haemoglobin

MEPPA – Multimedia Education Programme Patient Acceptability instrument

NHS – National Health Service

NICE – National Institute for Clinical Excellence

OGTT – Oral glucose tolerance test

REC – Research Ethics Committee

T2DM – Type 2 diabetes mellitus

WHO – World Health Organisation

1.0 INTRODUCTION

1.1 OVERVIEW

Diabetes mellitus is a chronic condition affecting increasing numbers of people worldwide and its incidence is increasing at an alarming rate. It currently affects 2.9 million people in the UK with a further 850,000 people estimated to have diabetes but remaining undiagnosed (Diabetes UK, 2012). This is estimated to rise to 4.6 million by 2030, with 90% of these being diagnosed with type 2 diabetes (Diabetes UK, 2012). Type 2 diabetes mellitus (T2DM) is characterised by raised blood glucose as a result of insulin resistance and declining pancreatic β cell function, resulting in reduced insulin secretion (NICE, 2011).

Diabetes and its complications are associated with significant morbidity and mortality, reducing a person's life expectancy by an average of 10 years (Roper, Bilous, Kelly, Unwin & Connolly, 2001), increasing the risk of depression (Jacobson, 1996) and reducing quality of life (Koopmanschap, 2002). Diabetes is the leading cause of blindness, kidney failure and non-traumatic lower limb amputations for people of working age. Furthermore, T2DM significantly increases the risk of cardiovascular disease and stroke, with a five fold increased risk compared to those without diabetes (Diabetes UK, 2012). T2DM also has significant economic implications for the UK; putting substantial strain on the health service; it currently costs the NHS over £10 billion per year, accounting for around 10% of the total NHS budget (Diabetes UK, 2014). This is projected to rise to approximately £20.5 billion by 2035 for costs both directly and indirectly related to the management of type 2 diabetes (Hex et al. 2012).

Risk factors for the development of type 2 diabetes include a high BMI, large waist circumference, increased age, a history of gestational diabetes, family history of diabetes and ethnicity (NICE, 2012). While some factors are not modifiable, such as age and genetics, evidence has shown that by addressing lifestyle factors, such as diet and exercise, through intensive lifestyle interventions, it is possible to significantly reduce the risk of developing type 2 diabetes in the future (NICE, 2012). Given the damaging health and financial implications of undetected hyperglycaemia, it is a priority to identify those at high risk of developing T2DM, in order to put prevention and early diagnosis strategies in place.

1.2 GESTATIONAL DIABETES

Gestational diabetes mellitus (GDM) is defined as carbohydrate intolerance resulting in hyperglycaemia of variable severity that begins or is first diagnosed during pregnancy (WHO, 1999) and currently affects 3-5% of pregnancies in the UK (Bentley-Lewis, 2009). If not managed effectively, gestational diabetes can result in serious complications for both mother and baby including macrosomia, shoulder dystocia, stillbirth and miscarriage (Bentley-Lewis, 2009). However, if blood glucose levels remain controlled throughout the pregnancy, the risk of these complications is significantly reduced (NICE, 2015). Blood glucose levels usually return to normal following birth, but subsequent pregnancies are very likely to be complicated with gestational diabetes again (Bentley-Lewis, 2009).

A history of gestational diabetes significantly increases the risk of progression to T2DM, carrying a 7-12 fold increased lifetime risk compared to women who had a normoglycaemic pregnancy, with the greatest risk in the first five years post

partum (Bellamy et al. 2009). Indeed, it is estimated that between one third and one half of women diagnosed with type 2 diabetes will have had a previous diagnosis of gestational diabetes (Cheung & Byth, 2003), providing a very important and reliable predictor of future type 2 diabetes and a target for prevention interventions.

Numerous studies have shown that progression to type 2 diabetes in high-risk groups, such as women with a history of gestational diabetes, can be delayed or prevented through an intensive lifestyle intervention (Aroda et al., 2014). However, additional research has found significant barriers to engaging this population of women in education and to changing and maintaining lifestyle behaviours (Stage, Ronneby & Damm, 2004).

1.3 EDUCATION IN DIABETES PREVENTION

The National Institute of Clinical Excellence (NICE) state the importance of implementing interventions to prevent or delay the progression of type 2 diabetes in high risk groups (NICE 2012) and have set out clinical guidelines for the management of diabetes in pregnancy (NICE, 2015) and for high risk groups (NICE, 2012) to indicate appropriate methods of intervention. Interventions involving an intensive lifestyle change programme have been shown to reduce the risk of T2DM in such high-risk groups by up to 50% (Knowler et al., 2002). The lifestyle programmes employed behaviour change strategies to encourage participants to make healthier food choices, increase physical activity and maintain a healthy body weight (Knowler et al., 2002).

1.4 EDUCATION FOLLOWING GESTATIONAL DIABETES

NICE recommends offering lifestyle advice to women with a history of gestational diabetes at postnatal follow up and annually thereafter (NICE, 2015). NICE Technical Appraisal 60 recommends that education sessions should be accessible to the broadest range of people and use a variety of techniques to promote active learning, adapted to meet the needs of the population (NICE, 2003). The use of lifestyle interventions in women with a history of gestational diabetes has been investigated (Ratner et al., 2008, Aroda et al. 2015, Tuomilehto et al., 2001, Pan et al., 1997), but many cite multiple barriers to attendance and lifestyle change, such as lack of time, fatigue and childcare issues (Nicklas et al., 2011). The use of multimedia education tools have been found to be effective in improving knowledge, health behaviours, clinical outcome and self-efficacy in people with chronic disease (Murray, Burns, See, Lai, & Nazareth, 2005). However, research investigating its use in women with a history of gestational diabetes is sparse and may address some of the barriers cited. The use of a multimedia education tool with women with a history of gestational diabetes has the potential to improve patient knowledge to implement lifestyle change and to reduce the risk of type 2 diabetes in the future.

1.5 THE RESEARCH PROJECT

The following study was designed to provide a formative evaluation to the utility of a tablet-based multimedia education programme for women with a history of gestational diabetes. This report explores the impact of gestational diabetes on the risk of type 2 diabetes, assesses methods of education and discusses the evidence surrounding multimedia education in this group. It describes the

methodology involved in programme development and presents the results from the formative evaluation with reference to relevance, usability, content and appearance of the programme to assess its suitability to proceed to clinical trial with formal users.

2.0 LITERATURE REVIEW

The following literature review examines in more depth the evidence surrounding the need for education within this population, how the delivery of patient education has evolved and assesses the evidence for multimedia education in patient groups.

2.1 GESTATIONAL DIABETES

2.1.1 PHYSIOLOGY OF GESTATIONAL DIABETES

While it is beyond the scope of this paper to go into depth concerning the metabolic changes during pregnancy, we must first consider the changes in glucose metabolism that take place in a normal pregnancy, and which of these modifications may contribute to the development of gestational diabetes mellitus (GDM) in order to understand the lifetime implications that follow. Glucose metabolism is altered as a natural adaptation in pregnancy in order to favour the supply of glucose to the foetus (Shao et al., 2000). It is characterised by impaired insulin sensitivity, increased pancreatic β cell response, increased postprandial blood glucose levels and alterations in lipid metabolism (Shao et al., 2000).

Despite a degree of insulin resistance in a normal pregnancy, a compensatory increase in pancreatic β cell function maintains normal glucose homeostasis (Di Cianni et al., 2010). GDM manifests when β cell insulin secretion can no longer counteract the level of insulin resistance. It is estimated that women with GDM have a 67% reduction in β cell function compared to normal pregnant women

(Xiang et al., 1999). While the precise mechanisms of these metabolic alterations remain unclear, evidence suggests that hormonal changes in pregnancy make a substantial contribution (Di Cianni et al., 2010), as well as a family history of T2DM and obesity (Di Cianni et al., 2010). In addition, TNF-α, an inflammatory cytokine has been found to be a powerful predictor of impaired insulin action in pregnancy and is also likely to contribute (Kirwan et al., 2002).

In the majority of cases, blood glucose levels return to normal following delivery, suggesting that placental hormones may have a strong influence on β cell function and insulin resistance (Buchanan & Xiang, 2005). Indeed, Di Cianni et al. (2010) found that the risk of future T2DM increases as a function of periods of exposure to insulin resistant states through further GDM pregnancies, possibly due to accelerated β cell function decline. Peters et al. (1996) suggests that a second pregnancy translates to a further three-fold increased lifetime risk of T2DM. In addition, factors such as diagnosis of GDM before the 24th week of pregnancy, increased BMI at time of diagnosis, impaired β cell function and insulin therapy also contribute to the increased risk of progression towards T2DM (Di Cianni et al., 2010). It is proposed that the altered metabolic state which pregnancy presents highlights an early warning sign for the progression of T2DM and further accelerates its progress through exposure to insulin resistant states (Di Cianni et al., 2010).

2.1.2 ASSESSING THE TRUE PREVALENCE OF TYPE 2 DIABETES IN WOMEN WITH A HISTORY OF GESTATIONAL DIABETES

Due to the lack of consistency in diagnostic tests and screening techniques it is challenging to assess the true prevalence of T2DM in women with a history of

GDM. Postpartum screening provides the opportunity to identify any undiagnosed cases of T2DM, but international recommendations for postpartum screening vary significantly. NICE (2015) recommends screening for T2DM at 6-13 weeks postpartum using fasting plasma glucose (FPG) test and to offer an annual HbA1c test for those who have a negative postnatal test thereafter. However recommendations from New Zealand endorse the use of an HbA1c test at three months post partum and annually thereafter (Ministry of Health, 2014), and recommendations from America suggest the use of an oral glucose tolerance test (OGTT) at 6-12 weeks postpartum and follow up testing every three years (American Diabetes Association, 2015).

Evidence suggests that a 75g OGTT is the most accurate method of identifying women with impaired glucose tolerance in the first year postpartum (Tandon, Gupta and Kalra 2015). The OGTT has a reported sensitivity of 100%, compared to 67% with the fasting blood glucose test (Tovar et al., 2011). However, due to the time-consuming nature of the OGTT, which requires a two-hour waiting period, a fasting blood glucose test, and multiple blood samples, the test may be unacceptable to many mothers with new babies and may contribute to poor attendance rates (Ministry of Health, 2014). NICE (2015) concluded that there was currently insufficient evidence to recommend the use of OGTT in routine postnatal screening.

Tovar et al. (2011) conducted a literature search of postpartum screening practices and found that between 34%-73% (median 48%) of women completed screening following gestational diabetes. Through further analysis, they found that screening rates were higher in the women of older age, having their first

child, with higher income, with a higher level of education, of Asian ethnicity, those who were treated with insulin during pregnancy and those who attended their six-week postnatal check up. The most frequently cited barrier to adhering to screening protocols cited by patients is lack of time (Keely et al., 2010), followed by financial pressures and inconvenience (Baker et al. 2009). Clinicians reported that the inconsistency of the screening guidelines and communication problems between obstetricians and primary care also presented barriers (Steube et al., 2010).

The strength of the association between gestational diabetes and type 2 diabetes, and the knowledge that the risk factors for each are similar (family history of T2DM, increased age, black/south Asian descent, raised BMI), suggest that the two disorders may have similar aetiology (Kim et al. 2002). Indeed, of those that complete postpartum screening tests, a number of factors have been found to be associated with an increased likelihood of an abnormal result. Women who have a family history of type 2 diabetes, who were diagnosed with gestational diabetes earlier in pregnancy, who required insulin during pregnancy, who are from a high risk ethnic group such as South Asian, who have a pre-pregnancy BMI >25kg/m^2 or who have a higher prenatal blood glucose were more likely to be diagnosed with either impaired glucose tolerance or type 2 diabetes. (McClean, Farrar, Kelly, Tuffnell & Whitelaw, 2010; Akinci et al., 2010; Baptiste-Roberts et al., 2009)

Increased risk of abnormal glycaemia appears to persist past the early postpartum period. Retnakaran et al. (2010) found that of 70 women with a diagnosis of GDM with a normal OGTT results three months postpartum, 17%

had either impaired glucose tolerance or impaired fasting glycaemia when re-tested at 12 months postpartum. Indeed, further evidence suggests that the risk for type 2 diabetes continues to increase over time following a GDM pregnancy. Ekelund et al (2010) found that at 5 years postpartum, 30% of women with GDM had developed type 2 diabetes and 51% had developed either impaired glucose tolerance or impaired fasting glycaemia. Furthermore, Chodick et al. (2010) conducted a retrospective cohort study investigating the incidence of type 2 diabetes in women with a history of gestational diabetes in Israel over a ten-year period and found that the cumulative risk of T2DM over ten years in women with a history of GDM was 15.7%, compared to 1% in women with no such history.

Bellamy et al. (2009) conducted a systematic review and meta-analysis of cohort studies investigating the rates of T2DM in women with a history of GDM and women with normoglycaemic pregnancies between 1960 and 2009. They collated results from 20 studies, including 675 455 women of whom 10 859 had a diagnosis of T2DM and concluded that women with a history of GDM carried a 7-12 fold increased lifetime risk of developing type 2 diabetes compared to women who had a normoglycaemic pregnancy. Further to this, they found that within five years of a GDM-complicated pregnancy, the relative risk of progressing to T2DM was 4.7, which increased to 9.3 in those women who had a GDM-complicated pregnancy more than 5 years postpartum, compared to women who had a normoglycaemic pregnancy. These results suggest that the relative risk of T2DM appears to rise sharply in the first 5 years following a GDM pregnancy. In addition, Kim et al. (2002) conducted a systematic review of follow up studies between 1965 and 2001 following up women with previous

GDM between 6 weeks and 28 years postpartum. The cumulative incidence of T2DM ranged from 2.6% to 70%, with incidence rising steepest in the first 5 years after delivery, with a slower progression subsequently (figure 2.1). Since the risk of T2DM seems to extend over several years postpartum, continuous screening and health assessment may be advantageous to identify other risk factors early. Further studies are required to assess the optimal screening frequency and method required, in order to put prevention and early diagnosis strategies in place.

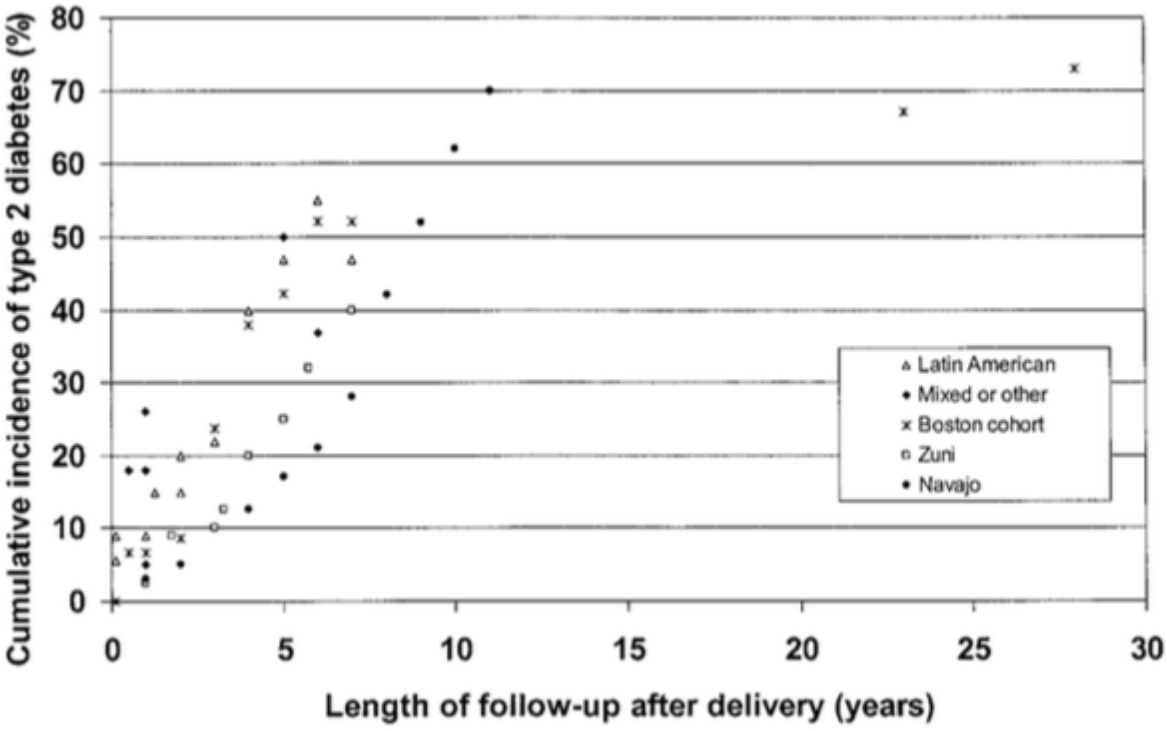

Figure 2.1 –Cumulative incidence of type 2 diabetes by length of follow up after delivery. From Kim et al. (2002)

2.1.3 PREVENTION INTERVENTIONS FOLLOWING GESTATIONAL DIABETES

NICE (2015) recommends that women who are diagnosed with T2DM following gestational diabetes should be referred to a specialist diabetes management

team, while women who have impaired glucose tolerance and normal results may benefit from lifestyle advice for diabetes prevention. Strong evidence is accumulating to suggest that the progression from GDM to T2DM can be delayed or prevented through lifestyle modification (Knowler et al., 2002). The Diabetes Prevention Programme (DPP) study (Knowler et al., 2002) is a randomised controlled trial comparing methods of T2DM prevention in high-risk adults, including women with a history of GDM. 3234 non-diabetic adults with elevated fasting or post-load plasma glucose levels were enrolled on the study and randomly allocated to either intensive lifestyle modification (goal of 7% maintained weight loss and 150 minutes physical activity per week), metformin (standard lifestyle recommendations plus metformin 850mg twice a day) or placebo (standard lifestyle recommendations plus placebo twice daily) groups. The average follow up was 2.8 years and the incidence of T2DM was 7.8, 4.8 and 11.0 cases per 100 person years in lifestyle, metformin and placebo groups respectively (Table 2.1). The lifestyle modification intervention reduced the incidence of T2DM by 58% (95%CI, 48-66) compared to placebo, while the metformin intervention reduced the incidence by 31% (95%CI, 17-43) compared to placebo (table 2.1).

	Cases of T2DM per 10 person years	Reduction in risk of T2DM compared to placebo (adjusted for age)
Intensive lifestyle	7.8	58%[a]
Metformin	4.8	31%[a]
Placebo	11	

Table 2.1 – Effect of Diabetes Prevention Programme on incidence of type 2 diabetes (Knowler et al., 2002)
[a] $p<0.05$ compared to placebo

In recognition of the increased risk that GDM carries for T2DM, Ratner et al. (2008) further investigated a subset of women with such a history recruited into the original DPP study. Of those enrolled in the study, 350 women were identified with a history of GDM (self-reported) and were paired with 1416 women with normoglycaemic pregnancies. Women were comparable in parity, BMI, ethnicity, fasting glucose, 2-hour post glucose load, HbA1c, insulin sensitivity and insulin secretion. The placebo group was used to estimate the cumulative incidence of type 2 diabetes with no interruption in progression of glucose intolerance. After three years, the cumulative incidence of type 2 diabetes in the placebo group was 38.4% for women with a history of GDM, compared to 25.7% in women with no such history (table 2.2). Indeed, women with a history of GDM were found to have a 71% increased 100 person-year incidence of developing T2DM compared to paired women without such history, despite statistically similar glucose levels at the start of the study.

	Cumulative Incidence after 3 years	Incidence of T2DM (number of cases per 100 person-years)*
GDM (n=122)	38.4% (n=47)	15.2[a]
Non-GDM (n=487)	25.7% (n=125)	8.9

Table 2.2 – Effect of Effect of Diabetes Prevention Programme on incidence of type 2 diabetes
*adjusted for age
[a] $p<0.05$ compared with non-GDM group

Among those with a history of GDM, Ratner et al. (2008) found that intensive lifestyle intervention (goal of 7% maintained weight loss and 150 minutes physical activity per week) reduced the incidence of T2DM by approximately 53% and metformin intervention (standard lifestyle recommendations plus metformin 850mg twice a day) reduced the incidence of T2DM by approximately

50% compared with placebo. Whereas there was a reduction in risk of 49% and 14% for lifestyle and metformin groups respectively when compared to women without a history of GDM (table 2.3).

	Non-GDM women	GDM women
Intensive lifestyle group	49%[a]	53%[a]
Metformin	14%	50%[a]

Table 2.3 –Reduction in incidence (compared to placebo and adjusted for age) following Diabetes Prevention Programme
[a] $p<0.05$ compared to placebo

From the data presented from the above study, we can see that intensive lifestyle intervention was similarly effective at reducing the incidence of T2DM in both groups of women (49% vs. 53%, $p<0.74$), while Metformin appears to have a greater effect on those with a history of GDM (14% vs. 50%, $p<0.06$). The increased efficacy of Metformin therapy in this group may be partly explained by the younger average age of the GDM group (mean GDM group: 43 years vs. 51.5 years non-GDM group). Crandall et al (2008) analysed the results of the DPP trial by age and revealed that while there was little difference in relative reduction between the intensive lifestyle group and Metformin groups in the 25-44 age range, there was no significant difference between Metformin and placebo for those over 60. In addition, they revealed that younger groups were more likely to have higher waist circumference, BMI, insulin secretion and insulin resistance.

2.1.4 BARRIERS TO REACHING THIS POPULATION

While lifestyle intervention in this high-risk group has been found to be advantageous, evidence shows that there are significant barriers to reaching this population and to them achieving and maintaining behaviour change. Little

attention has been given to the factors that may influence behaviour change; risk perceptions and health beliefs in this population (Jones, Roche and Appel, 2009).

Kim et al. (2007) conducted a questionnaire study on health beliefs in women with a history of GDM. They found that while 90% of women were able to identify GDM as a risk factor for T2DM, only 16% believed that they were at a high risk of developing T2DM in the future. When asked what their risk would be if they made no lifestyle changes, still only 39% identified that they would be at high risk. The findings of this study identify a gap between knowledge and accurate risk perception in this population of women. This is consistent with the health belief model, which proposes that an accurate risk perception and understanding an individual's health beliefs may predict health behaviour change (Becker, 1976). For example, to make a behaviour change a woman must firstly accurately identify a history of GDM as increasing her risk of getting type 2 diabetes in the future, secondly, must understand the required changes in lifestyle necessary to reduce her risk, thirdly, must see that the benefits to making the behaviour change outweigh the negatives and barriers and finally that the woman must feel able and confident in her ability to make the behaviour change (self-efficacy). A limitation of this study is that due to it's cross-sectional design, no information is given on actual behaviour change achieved, therefore longitudinal studies are required in this area to further investigate this (Jones, Roche and Appel, 2009). Additional further studies have demonstrated that women with a history of GDM are no more likely to participate in physical activity and healthy diet behaviours than women following a normoglycaemic pregnancy (Swan et al, 2007; Kieffer et al. 2006; Smith et al.,

2005), despite reporting being more worried about their own health and rating their children as less healthy (Feig et al. 1998).

Women with a history of GDM cite myriad barriers to making healthy behaviour changes such as insufficient time, lack of childcare and fatigue (Symons-Downs and Ulbrecht, 2006, Nicklas et al., 2011). Indeed, in a postpartum weight loss trial involving group meetings and exercise classes, despite all participants stating they were enthusiastic to take part, participants only attended an average of 3.8 sessions out of 18 and 43% failed to attend a single session (Ostbye et al., 2009). Nicklas et al (2011) used a focus group and interview technique to find methods of overcoming these barriers. All focus group members agreed that time constraints were a significant barrier to attending scheduled group sessions such as those in the DPP trial, but identified that that internet based education may allow flexibility in learning and a one-on-one lifestyle coach would be useful to maintain motivation and help to answer specific questions.

A significant limitation with the DPP Trial is that the women identified as high risk due to a history of GDM had their first GDM pregnancy an average 12 years previously. As a result, the barriers which face women in the first year post-partum are very likely to be different from those 12 years post partum. In addition, the risk of T2DM increases most steeply within the first 5-10 years of GDM pregnancy (Kim et al., 2002); therefore the DPP trial may have excluded those at the highest risk. Therefore, while the study shows that an intensive lifestyle intervention in this group may be effective in reducing the risk of T2DM,

it may not be the most appropriate method in achieving health behaviour changes in women shortly after a GDM pregnancy.

2.2 PATIENT EDUCATION

Patient education is a means to provide information to improve knowledge and skills to enable patients to maintain and improve their health (Rankin, 2001). This may include knowledge of treatment options, how to effectively use their medication or teaching self-management skills (Rankin, 2001). Providing patients with information about their condition has been found to help provide a sense of control and increases patient participation in shared decision making with clinicians (Davison, Goldberg, Gleave & Degner, 2002). Shared decision making is a patient-centred approach and aims to fulfil the active engagement of patients in decisions regarding their health (Barry & Edgman-Levitan, 2012).

2.2.1 EVOLUTION OF PATIENT EDUCATION

Within the past twenty years there has been a great evolution in the provision of patient education and with it a change in the relationship between a clinician and patient. Patients are demanding more information about their health than ever before and are showing increased interest in participating in making health decisions (Hannah et al., 1989, Sheppard, Coulter & Farmer, 1995).

Traditionally, education has been delivered through face-to-face consultations with clinicians (Katz & Moyer, 2004), with the clinician being regarded as the 'expert', with patients playing a passive role (Bodenheimer, Lorig, Holman & Grumbach, 2002). Evidence suggests, however, that often patients do not fully understand what is being said and frequently ask fewer questions in a

consultation room environment and often have poor recall if information provided (Ishikawa et al., 2009). This form of education is often delivered in a clinic environment, requiring significant professional time, space and clinical expertise (Jones, Nyhof-Young, Friedman & Catton, 2000). Written information, in the form of leaflets, books or hand-outs can help to reduce the time pressure on physicians and support verbal information supplied (Jones, Nyhof-Young, Friedman & Catton, 2000). However, these resources are often expensive to order and update and the reading level is often not appropriate for the target audience (Flynn et al., 2004).

During the past decade, increasing numbers of people are using the Internet to access health related information (Cotten and Gupta, 2004). The main advantage to this medium is the increased availability of information, with 77% of the UK population having access to broadband connection as of 2014 (OFCOM, 2014). However, while some websites are written and updated by healthcare professionals, there is also a wealth of inaccurate and out-of date information available (Boulos, 2004). Moreover, as with written information, it holds a significant disadvantage of being limited to those with relatively high health literacy. Boulos (2005) assessed the reading age of resources for diabetes mellitus available on the Internet and found that the average reading age for a resource was 14.2 years old, with NHS Direct scoring a reading age of 17.8 years and Diabetes UK scoring 14.8 years, which is significantly higher than the UK average reading age of 9 years old (Boulos, 2004).

Cooper, Booth, Fear & Gill (2001) conducted a descriptive meta analysis, combining results from 12 previous meta-analysis reporting the cumulative

efficacy of 565 interventions involving patient education in chronic disease which required behaviour modification. They concluded that there was an overall advantage to patient education, however found wide ranging study protocols and poor description of educational interventions. They concluded there was a need for further research to elucidate the specific learning processes required to achieve optimal knowledge transfer. Some of the inconsistencies noted in Cooper, Booth, Fear & Gill (2001) are thought to be related to the significant challenges which healthcare providers face when trying to provide effective patient education. These challenges include finding or developing resources that contain relevant, up to date information in a format that is acceptable and accessible to a wide range of patients with ranging learning, language and cognitive abilities.

One significant challenge to overcome within patient education and self-management is low health literacy (Williams, Baker, Parker & Nurss, 1998). Health literacy is defined as ‘‘…the degree to which individuals can obtain, process, and understand the basic health information and services they need to make appropriate health decisions’’ (Kindig, Panzer & Nielsen-Bohlman, 2004, p. 31). In the UK, 5.2 million adults have low levels of literacy skills (Boulos, 2005), and patients may not relay this difficulty to their healthcare professional (Kripalani & Weiss, 2006). Moreover, evidence has found that there is a direct link between health outcomes and low health literacy, such as hospitalisation and use of emergency services (Cho, Lee, Arozullah & Crittenden, 2008), particularly in those with chronic diseases (Schillinger et al., 2002).

In addition to the challenges faced in delivering patient education, healthcare provider's resources have come under significant financial pressure, which has resulted in budget cuts and staff reorganisations which have put barriers in the way of further development of patent education (Davis & Chesbro, 2003). This challenging environment has meant that healthcare providers must take a more strategic and streamlined approach to produce a cost- and time-effective medium of engaging, interesting and up-to-date information to a diverse population with wide ranging learning styles, while tailoring the program content to individual needs; a prospect which may seem insurmountable.

2.2.2 INCREASING ACCESSIBILITY THROUGH TECHNOLOGY

Mobile technologies, such as mobile phones, smart phones, media players (mp3s) and tablet PCs have been used with some great success within many settings including in schools, workplace training and healthcare (Jiao & Chen, 2011; Coulby, Hennessey, Davies & Fuller, 2011; Fox, 2005). Over 60% of the UK's population now owns a smart phone and 77% of the UK population has access to a broadband connection (Lakshinarayana et al., 2014). Features of mobile technologies, such as their popularity, portability and technical capabilities make them particularly appealing to providing health care support and education to a large population.

As time has progressed, technology has advanced to a level where computers, tablets and smart phones are more powerful and have increased capacity for memory and graphics, making more technologically advanced programmes possible. These technological advancements increase the capacity for interactivity with the programme with features such as touch screens, which

may further engage the user with the programme. Further to this, the cost of these products has significantly reduced and the availability of Internet access and high-speed broadband connections has increased in recent years, making these products increasingly accessible for a wide population. A recent systematic review on the use of mobile phone technology in healthcare found that the use of voice and text-messaging services are effective in improving health outcomes in a variety of conditions; including increasing medication compliance, stress management, smoking cessation and reducing missed appointments (Krishna, Boren & Bales, 2009).

2.2.3 MULTIMEDIA PATIENT EDUCATION

The use of interactive, computer-based programmes have emerged as an alternative method of patient education in an attempt to overcome some of the challenges faced by healthcare providers. The use of multimedia technology within education is based on the constructivist learning theory; which states that meaningful learning takes place when users take an active part in the learning experience by selecting relevant information, organising it into their own set of beliefs and integrating it with other knowledge (Mayer & Moreno, 2002).

A multimedia programme is an application that combines the use of text, graphics, sound, animation, videos and interactivity to enhance users experience and facilitate learning (Flynn et al., 2004). As multimedia programmes covey information in such a variety of ways, it has the potential to appeal to people with a wide range of learning styles, for example interactive components and the use of videos appeals to active learners, while visual learners prefer the visual navigation through the programme, pictures, words

and videos (Montgomery, 1995). Multimedia education may be of particular benefit to those with low literacy ability, or to whom English is a second language (Jones, Nyhof-Young, Friedman & Catton, 2000). Patients are free to proceed through the programme in their own time, allowing self-paced learning and repetition (Jones, Young, Friedman & Catton, 2000). In addition, since a user is able to view and repeat the programme as many times as required, with minimal or no healthcare staff involvement, it represents a potentially cost effective mode of education delivery (Alessi & Trollip, 2001).

Despite potential benefits of computer-based programmes for patient education, very few studies focus on the evaluation of such programmes. In review articles analysing computer and multimedia based patient education systems Lewis (2003), Wofford, Smith & Miller (2005) and Fox (2009) found only 78 articles collectively between 1971 and 2008, with only 26 of them fulfilling multimedia criteria. Lewis (2003) updated the earlier Lewis (1999) review and analysed 32 research studies published investigating the efficacy of computer based patient education between 1971 and 2001. Wofford, Smith & Miller (2005) then further updated this review to include 26 studies investigating multimedia computer based education programmes prior to 2004. Fox (2009) further examined the literature for investigating the impact of 25 computer-based patient education programmes published between 2000 and 2008. All reviews found that in the majority of cases, computer based education programmes resulted in increased patient knowledge, however other clinical and attitudinal outcomes were highly variable. While it was concluded that there was significant potential within computer-based education, further research was required to further investigate the clinical and economic related outcomes.

Evidence shows that when compared to traditional face-to-face education, a well-designed, interactive multimedia programme appears to be equally or more effective across a variety of disease states including HIV (Evans, Edmondson-Drane & Harris, 2000; Marsch & Bicket, 2004), cardiac rehabilitation (Jenny & Fai, 2001), schizophrenia (Jones et al., 2001), carpal tunnel syndrome (Keulers et al., 2007), colposcopy (Martin et al., 2005) and faecal occult blood screening (Miller et al., 2005) (table 2.4). It has also been found to be effective across a number of different tasks including providing medical information (Gustafson et al., 1994), teaching self-management skills (Wetstone et al., 1985) and promoting patient decision-making (Barry et al., 1995; Kasper, Mully & Wennberg, 1992). For example, Jenny & Fai (2001) compared a computer-based education programme to a clinician-led tutorial group in patients undergoing a cardiac rehabilitation programme. They found that the computer group had significantly higher knowledge after the intervention compared to the tutorial group, however found no difference in self-efficacy between groups. Further to this, Stromberg, Dahlstrom & Fridlund (2006) conducted a trial comparing knowledge, quality of life and compliance in heart failure patients assigned to either standard education or standard education in addition to a computer based education programme. They found both groups had significantly increased knowledge one month after the education session, with a trend for higher knowledge retention in the computer based education group. After 6 months however, the increase in knowledge in the computer based education group was significantly higher than in the standard education group, suggesting that the computer based education may be more effective at getting

users to retain knowledge for longer, however further research is required to further investigate this effect.

Reference	Education topic	Outcomes	Control vs. treatment group
Evans, Edmondson-Drane & Harris (2000)	HIV prevention	Computer based programme more effective in increasing knowledge, motivation and prevention behaviour	Lecture vs. computer based programme vs. no treatment
Jenny & Fai (2001)	Cardiac rehabilitation	Computer group had significantly higher knowledge, however no difference in self-efficacy compared to the tutorial group.	Tutorial vs. computer based programme
Jones et al. (2001)	Schizophrenia	No significant difference between groups for knowledge, cost and psychological state	Computer programme vs. nurse educator vs. programme +nurse
Keulers et al (2007)	Carpal tunnel syndrome	Computer programme group had significantly higher knowledge. No impact on patient satisfaction	Computer programme vs. physician counselling
Martin et al (2005)	Colposcopy	Computer programme group had significantly higher knowledge. No impact on patient satisfaction	Computer programme vs. nurse educator
Marsch & Bicket (2004)	HIV/AIDS education for injection drug users	Computer programme group had significantly higher knowledge and significantly reduced risk behaviours	Computer programme vs. counsellor
Miller et al. (2005)	Faecal occult blood screening	Computer programme group had significantly higher knowledge. Both groups have significantly increased screening prevalence.	Computer programme vs. nurse counsellor
Green et al (2004)	Breast cancer genetic screening	Computer programme group had significantly increased knowledge and self efficacy, however genetic counsellor group had lower anxiety and more accurate risk perception	Computer programme vs. genetics counsellor

Table 2.4 –Comparison of research studies examining the efficacy of computer education programmes

While results from such studies hold promising potential, results of some studies, such as Green et al. (2004) who compared the use of a computer based education programme with education with a genetics counsellor with the aim of educating women on genetic screening for breast cancer raise a cause for concern for computer based education replacing contact with a clinician for

education entirely. While the computer programme was effective in increasing knowledge and self-efficacy in patients above that of the genetics counsellor session, results showed that levels of anxiety and accurate perception of risk was lower in the computer group. Taking this into account, it was concluded that properly designed computer education systems may be an effective supplement to patient education, which have the potential to reduce costs and staff pressures, however not replace face to face contact with clinicians for education entirely (Stoop, Riet & Berg, 2004). Further to this, some healthcare professionals have expressed concern that the use of computer based education programmes, and therefore the reduction in time spent with a clinician may have detrimental effects on patient satisfaction and acceptance. However, evidence suggests that computer based education programmes have found little impact on patient satisfaction, with patients rating that they were equally satisfied with both the computer based education and the face-to-face education (Martin, Hoffman & Kaminski, 2005; Keulers et al., 2007).

Not all multimedia programmes, however, are implemented successfully. Stoop & Berg (2001) evaluated a patient information system designed to give medical information on a range of conditions and provide a medical encyclopaedia. The system was set up in a waiting room of a GP surgery and the efficacy and efficiency of the programme was measured through observation and interviews with patients. Following initial testing however, it was found that the programme was hardly used. It was concluded that the main reason for the failure of this programme was that there was a large gap between what the designers assumed the users needed or wanted to know and what the users actually needed and wanted. Stoop, Van't-Riet & Berg, 2004 proposes that one must

consider the emotional and cognitive content of the programme, the moment of implementation relative to the moment in the illness course and the setting and context of use. Unfortunately, in this example, Stoop and Berg (2001) failed on all three components. Stoop and Berg (2001) made the assumption that the information system could replace the GP as an information source, in order to free up consultation time, however, they overlooked the fact that patients seek more than just information from a clinician; many patients want to be reassured and to talk to someone (Grol et al., 1999). They also made the assumption that the patient knows what type of information to search for and have the ability to interpret the information themselves. However, research shows that many patients attend their GP because they do not know what is wrong and are seeking the opinion of an expert and are therefore often unable to search and interpret the information alone (Richards, Colman & Hollingsworth, 1998; Van de Kar, Knottnerus, Meertens, Duboir & Kok, 1992). Further to this, patients commented that if they were going to seek information about a condition, they would do it at home before making an appointment with a GP; and therefore felt that the timing of the intervention was inappropriate. Finally, Stoop and Berg (2001) placed the information system on a desk in the waiting room of a GP practice, where everyone was able to see the screen. The justification was that patients could use the programme to 'kill time' while waiting, however feedback from patients reported that this setting put them off from using it, especially if looking up sensitive topics (Hawthorne, 1994) and felt a more private setting would be more appropriate.

2.2.4 MULTIMEDIA PROGRAMMES IN POSTPARTUM WOMEN

The Internet and computer-based programmes have become an increasingly popular method of obtaining health information, especially for new mothers (Hearn, Miller & Lester, 2004), which make it an interesting method of delivery to explore. Hearn, Miller & Lester (2004) conducted a feasibility study for an online health information website and app to provide health information to perinatal women. The web programme contained information on nutrition, physical activity, weight, managing emotions, social life as a new parent and sleeping patterns and the supporting app provided a self-management programme for tracking health behaviour changes during pregnancy and during the first 18 months postpartum. They did not conduct a formal evaluation of the programme, however analysed website usage using Google analytics [Google, Mountain View, CA, USA] and concluded that the platform of using a web programme and app was effective at reaching this population of women.

Previous studies have demonstrated that computer based programmes are effective in encouraging postpartum women to make a variety of health behaviour changes including weight loss (Nicklas et al., 2014), managing postpartum depression (Danaher et al., 2013; Maher, Ziviani, Miller, Olds, & Parkyn, 2012) and breastfeeding (Cowie, Hill & Robinson, 2011). However have proved ineffective in encouraging physical activity in the postpartum period. For example, Gray (2014) developed and evaluated a web-based physical activity intervention for postnatal women. It consisted of an eight week programme of group exercise sessions and a website which displayed motivational and behavioural skills videos, a goal setting and self-monitoring calendar and a discussion board to support the group sessions. They found that

the web-based programme was acceptable and feasible to this population of women and interacted will with the face-to-face group exercise component and found that at the end of the intervention, self-reported physical activity had increased, however when measured objectively using an accelerometer, it was revealed that participants made no statistically significant change in physical activity levels from baseline to post intervention.

Few interventions have evaluated the use of computer based patient education programmes in women with GDM or following gestational diabetes. This population of women present unique barriers to education and health behaviour change that has thus far proved a challenge to traditional forms of education. Web-based programmes have been employed in the past to provide health information (Carolan-Olah, Steele & Krenzin, 2015), increase physical activity (Gray, 2014; Kim, Draska, Hess, Wilson, &Richardson, 2012) and reduce postpartum weight retention (Nicklas et al. 2014) within this population. Carolan-Olah, Steele & Krenzin (2015) developed an information website for multi-ethnic women with GDM. Twenty-one women were recruited and were assessed for general user-friendliness and acceptability of the programme and knowledge of GDM, food values and self-management principles using a pre-test and post-test questionnaire design. Overall, the women reported that they found the programme useful, easy to use and felt it was an effective way of presenting information. The website was effective at increasing knowledge of GDM in 70% of the participants and noted a small improvement in knowledge of food values and self-management principles. Further to this, Kim et al. (2012) investigated the efficacy of a web-based pedometer programme for women with a recent history of GDM. Women were split into intervention (13-week programme

providing web-based education, pedometer messaging and an internet forum) and control groups (no additional education or materials) and had their blood glucose levels measured between baseline and follow-up. No significant changes in either physical activity, blood glucose levels or body weight were noted in either intervention or control group. It was concluded that while this study indicated that it was feasible to introduce a web-based pedometer in this population, this study showed that this intervention was not effective in yielding a clinically meaningful impact.

To our knowledge, only one study has analysed the efficacy of a web-based multimedia lifestyle intervention in women following gestational diabetes. Nicklas et al. (2014) conducted a randomised controlled trial using a modular web-based lifestyle intervention to 75 women with a recent history of gestational diabetes over a 12- month period called 'Balance after Baby'. The primary outcomes of the study were change in body weight from first postpartum weight and self-reported pre-pregnancy weight. Secondary outcomes included calorie intake measured using a diet diary and physical activity measured using a pedometer and uptake of gym membership. Participants in the intervention group were offered access to a 16-module lifestyle modification programme adapted from the Diabetes Prevention Program (Knowler et al. 2002) and frequent contact from a lifestyle coach via telephone or email. Nicklas and colleagues attempted to overcome barriers to participation by providing laptops and internet access to those who did not have them and encouraged techniques such as goal setting and self-management techniques by supplying an online goal tracker and providing measuring cups, spoons, pedometers and complementary gym memberships to those who required them. The control arm

did not receive any additional information to support weight loss above the written information given at recruitment. Women allocated to the intervention group lost significantly more weight compared to the control group, with the intervention group losing an average of 2.8kg at 12 months postpartum compared to baseline, compared to the control group who still remained an average of 0.5kg above baseline weight. As weight retained at 12 months is highly predictive for future obesity, they concluded that these findings of a 3.3kg difference between groups are of clinical significance. The study also demonstrated that a web-based lifestyle intervention is feasible and acceptable in this population of women with a recent history of gestational diabetes.

2.2.5 MULTIMEDIA PROGRAMME PLATFORM

Previous studies have used web-based platforms (Nicklas et al., 2014; Flynn, van Schaik, van Wersch, Ahmed & Chadwick, 2004; Lee, Park, Yun & Chang, 2013; Jones, Nyhof-Young, Friedman & Caton, 2001; Kim, Draska, Hess, Wilson & Richardson, 2011), CD-ROMS (Stromberg, Dahlstrom & Fridlund, 2002; Ronning, Nielsen, Stromberg, Thilen & Swahn, 2013) and video (Albert, Buchsbaum & Li, 2007) to develop their multimedia programme. 'Keeping Healthy after Gestational Diabetes' multimedia education programme was developed on an HTML platform to function primarily on a tablet computer. The programme was developed to function without the need for Internet access, which allows for greater portability and flexibility compared to a web-based programme. As HTML coding is also common to website development, this design is not only flexible to use both on a tablet or computer with touch screen capabilities but can also be supported on a website and interacted with through the use of a mouse.

2.2 THE RESEARCH PROJECT

This paper reports on the development process and initial testing of a tablet based multimedia programme ‘Keeping Healthy after Gestational Diabetes’. The aim of the programme was to support women with a recent history of gestational diabetes to make lifestyle changes with the view to reduce the risk of type 2 diabetes in the future. This stage of the project aimed to evaluate the relevance, usability, content and appearance of the programme and also to identify any issues with the programme prior to proceeding to clinical trial.

3.0 METHODOLOGY

3.1 OVERVIEW

This feasibility study examined the development and initial evaluation of the multimedia programme 'Keeping Healthy after Gestational Diabetes'. The programme was developed using the five-stage system development life cycle: identification of patient requirements, system design, system development, system evaluation and finally system application, adopted from Kyung Lee et al. (2013). Formative evaluation was conducted using a mixed methods approach with the aim of assessing the relevance, usability, content and appearance of the programme and to identify any issues with the programme prior to proceeding to clinical trial. Quantitative data in the form of self-completed questionnaires were completed to assess the above variables following the completion of each module. Qualitative open questions within the questionnaire were used to collect information on elements of the programme users particularly enjoyed or felt required further development. The setting was the diabetes unit at the Countess of Chester NHS Foundation Trust (COCH), a district general hospital based in the North West of England.

3.2 ETHICAL APPROVAL

Ethical approval has been obtained through NHS Research and Ethics Committee (REC) and was approved by the Wales REC 4 committee as meeting ethical standards for high quality, safe and ethical research (appendix 1).

3.3 STAGE 1: IDENTIFICATION OF USER REQUIREMENTS

The requirements of the programme were based upon overcoming some of the barriers faced by the target population of women with a history of gestational diabetes. As described previously, this population face myriad barriers to attending education sessions, including lack of time, fatigue and lack of childcare (Downs and Ulbrecht, 2006). In addition to this, experience from the Diabetes Specialist Team at the Countess of Chester Hospital NHS Foundation Trust found that group education sessions were poorly attended and there was a lack of capacity to arrange one-to-one appointments for education.

As a result of this experience, in addition to a review of the literature, it was felt that a multimedia education programme might meet the needs of this population. The functional requirements of the programme included flexibility and portability. In order for the programme to be as flexible and portable as possible, it was decided to develop the programme to function on a tablet computer and without the need for Internet access and to break down the content of the programme into 10-15 minute modules.

Content requirements of the multimedia education programme were established through interviewing a multidisciplinary group consisting of a consultant physician specialising in diabetes, four dietitians and a senior lecturer in nutrition and dietetics In addition, content was decided through a review of current guidelines on postnatal education following gestational diabetes (NICE, 2015; NICE 2012) and broadly based upon previous group education offered to women with a history of gestational diabetes at the Countess of Chester NHS Foundation Trust.

Members of the multidisciplinary group were questioned regarding the information the programme should include to support a woman with a history of gestational diabetes. Key points are listed below:

- Increased awareness of the health risks following gestational diabetes
- Education about the development of / risk factors associated with type 2 diabetes
- Improved knowledge on lifestyle changes to avoid / delay onset of type 2 diabetes
- Education on a healthy balanced diet and portion sizes
- Education and ideas to increase physical activity with a new baby
- Increased awareness of the risk for future baby health
- Education on basic weaning practices
- Information about follow up care after gestational diabetes
- Increased awareness of warning signs of type 2 diabetes

Programme content requirements were also based upon current clinical guidelines (NICE, 2015) including:

- Explanation of long and short term effects of GDM to mother and baby
- Remind women of symptoms of hyperglycaemia
- Risk of gestational diabetes in future pregnancies
- Offer lifestyle advice – weight control, diet and exercise

Following this, the content was divided into seven modules and the team decided on the best way to present each section of information; incorporating text, audio, animation, 2D/3D graphics, interactive games and videos.

3.4 STAGE 2/3: SYSTEM DESIGN AND DEVELOPMENT

The programme content was initially written using Microsoft Word [Microsoft, Washington, DC, USA] and the overall appearance and navigation was designed using Microsoft PowerPoint [Microsoft, Washington, DC, USA] with reference to the content and functionality requirements established.

The tablet based multimedia education programme contained seven modules, including the introduction, health, diet, lifestyle, baby health, life after GDM and warning signs. The six main modules were accessed through a home screen (figure 3.1). The description of each module within the programme is described in table 3.1.

Figure 3.1 – home screen

Following this, a web developer [Footsqueek Ltd., Chester, UK] then built the multimedia programme using these specifications to function on an Apple iPad [Apple, Cupertino, CA, USA]. The programme was developed on Microsoft Windows [Microsoft, Washington, DC, USA] and written using pure HTML coding, which was then embedded into an iOS App using Xcode 6 [Apple, Cupertino, CA, USA]. Photoshop 8.0 [Adobe Systems, San Jose, CA, USA] and Adobe Creative suite 6 [Adobe Systems, San Jose, CA, USA] were used for all graphics and web design.

A voiceover was recorded and images obtained from stock and uploaded using Adobe Creative suite 6 [Adobe Systems, San Jose, CA, USA] and embedded into the programme as described above. Written consent was obtained for pictures that were obtained from personal sources and from those who appeared in the videos featured in the programme (appendix 9). The programme was operated on an Apple iPad Mini [Apple, Cupertino, CA, USA] and participants navigated through the programme using simple touch screen buttons.

Module title	**Description of content**
Introduction	• Aim of the programme • How to navigate the programme • Information on the oral glucose tolerance test
Home screen	• Allows navigation around the 6 main modules
Health	Risk of type 2 diabetes • Risk of developing type 2 diabetes following gestational diabetes • Risk factors for type 2 diabetes Healthy weight • Healthy weight • Video animation describing carbohydrate metabolism and physiology of diabetes
Diet	Healthy balanced diet • Food groups interactive game • Food groups and portion sizes Everyday eating • Interactive calorie game • Build a meal game – making healthier meal choices Quiz Top tips
Lifestyle	Post natal exercise class video with interview with new mum Video of NHS midwifes - physical activity advice Interactive balance scales activity
Baby Health	Starting solids • 4 stage weaning advice table • Drinks • Foods to be aware of Future health Quiz
Living post GDM	• Video of woman with a history of gestational diabetes describing lifestyle changes made after pregnancy.
Warning signs	• Follow up care following GDM • Warning signs to look out for – symptoms of type 2 diabetes

Table 3.1– description of the content of the 7 programme modules

3.5 STAGE 4 - SYSTEM EVALUATION

3.5.1 PARTICIPANTS:

Twenty patient representatives and twenty-two experts were recruited to conduct the initial evaluation of the multimedia programme. To meet inclusion criteria for patient representatives participants were required to be either a female of childbearing age (aged 18-45) or a female with a diagnosis of type 1, type 2 or gestational diabetes. To meet inclusion criteria for the expert panel participants were required to be either a healthcare professional or considered an expert in a related field (healthcare / physical activity / IT etc.). Exclusion criteria included any young person under the age of 18, those unable to communicate in English and those unable to give informed consent.

Participants were asked to read the 'Participant Information Sheet' (appendix 3), which detailed the nature and risks involved in the study. They were then given the opportunity to ask any questions prior to giving informed consent through signing the consent form (appendix 2).

3.5.2 DEMOGRAPHICS QUESTIONNAIRE

Basic demographic information was collected at the time of initial evaluation including gender, age, educational attainment, professional title (expert group only), computer skill level and iPad skill level (appendix 4).

3.5.3 MULTIMEDIA PROGRAMME

Participants were provided with an iPad Mini with the programme pre-loaded and a set of headphones. Following this, the researcher briefly explained how to

navigate the programme. Participants were also given an evaluation questionnaire to fill in throughout the programme. The researcher advised the participant to complete one module on the iPad and then immediately fill in the corresponding section of the questionnaire to avoid confusion between modules.

3.5.4 QUESTIONNAIRE – MEPPA - EVALUATION OF A PROTOTYPE

The multimedia education programme patient acceptability (MEPPA) – evaluation of a prototype instrument was designed to assess the relevance, usability, content and appearance of 'Keeping Healthy after Gestational Diabetes' multimedia education programme (appendix 6 / table 3.2). Acceptability is defined as how users may perceive the programme as suitable, through measures of appropriateness or participant satisfaction (Bowen et al., 2009). Relevance is defined as "The ability to retrieve information that satisfies the needs of the user" (Merriam-Webster dictionary). Usability is defined as "the extent to which a product can be used by specified users to achieve specific goals with effectiveness, efficiency and satisfaction in a specified context of use" (ISO 9241, 1998) Content is defined as "The topics or matter treated in a written work" (Merriam-Webster dictionary). Appearance is defined as "all visual attributes of a substance or object" (ISO 5492, 2008). The questionnaire content is shown in table 3.2.

The multimedia education programme patient acceptability (MEPPA) – evaluation of a prototype instrument was adapted with permission from a tool designed by Ronning et al. (2013) (appendix 5), which was developed to evaluate a computer based educational programme for adults with congenitally malformed hearts. The questionnaire was used to measure the usability,

comprehensibility and appearance of the content of the computer programme (Ronning et al., 2013). The instrument was trialled on a group of 49 formal users with congenitally malformed hearts in Sweden and Norway. Unfortunately, Ronning et al. (2013) did not comment of the internal consistency or validity of the questionnaire used.

	Questions	How measured
Relevance	I feel that the content of the **[x] module** is relevant to a patient with a history of gestational diabetes	Graded 1(strongly disagree) -4 (strongly agree)
Usability	The **[x] module** of the multimedia education program is easy to use The **[x] module** of the multimedia education program is easy to orientate	Graded 1(strongly disagree) -4 (strongly agree)
Content	The content of the **[x] module** of the multimedia education program kept me interested throughout The content of the **[x] module** of the multimedia education program is too advanced / too in depth The content of the **[x] module** of the multimedia education program is too basic	Graded 1(strongly disagree) -4 (strongly agree)
Appearance	How do you grade the amount of text used in the **[x] module** of the multimedia education program. How do you grade the graphic / animation content of the **[x] module** of the multimedia education program How do you grade the interactivity of the **[x module** of the multimedia education program How do you grade the overall appearance and design of the **[x] module** of the multimedia education program	Graded 1(very bad) -4 (very good)
Open questions	What did you like about the **[x] module**? Suggestions for improvement for the **[x] module**	Free text

Table 3.2 – Content of the questionnaire

The data collection for the patient representatives was supervised by a researcher and conducted at a location that was convenient for them (e.g.

waiting room, university library, clinic room). Data collection for the expert group was conducted either at the participant's place of work or the home of the participant. The researcher fully briefed the participants as above and was available (either in person, or telephone) to answer any queries. The questionnaire and programme session lasted approximately 60 minutes.

3.5.5 DATA MANAGEMENT AND ANALYSIS

Sample characteristics were presented for demographics. Questionnaire data was scored on a 4-point scale, ranging from 1 (strongly disagree/ very bad) to 4 (strongly agree/ very good). The scoring for questions 5 and 6 were reversed, thus, a greater score reflects greater satisfaction. Mean and standard deviation scores were taken for each measure (relevance, usability, content, appearance) overall and across expert and patient representative groups for each module.

Open-ended questions were analysed using qualitative content analysis developed by Mayring (2007), which divides analysis into three distinct phases; summary, explication and structuring. Summary involves reducing the data through paraphrasing and generalising to preserve the relevant content while still reflecting the original material. For this process, the material was extracted by the researcher and summarised into tables for each module and each group. Explication involves the process of uncovering the broad context of the material. Material was divided into positive comments, negative comments and suggestions for improvement. Structuring involves filtering themes from the material. The material was first colour coded according to the questions asked in the first part of the questionnaire (relevance, usability, content and appearance). Following this, further sub-themes developed such as interactivity and emotion and further explored the specifics of what the users liked or

disliked about the programme, such as the use of video, audio and using real-life accounts.

3.6 STAGE 5: SYSTEM APPLICATION

The programme developed was be applied to formal users in a further interventional study to investigate the programme's effect on knowledge, self-efficacy and patient acceptability in women with a history of gestational diabetes.

3.7 DATA PROTECTION

Data was held in accordance with the NHS Confidentiality Code of Practice and the Data Protection Act (1998). Data relating to the participants was held in locked filing cabinets in pin-code entry locked offices within the research site. Electronic data relating to participants was stored on NHS computers within limited access folders on a computer network with a password-protected login.

Participants involved in the research study were assigned a subject number, which will be used exclusively throughout the research on documents containing participant s personal information, and recorded on source data relating to the participant e.g. Completed questionnaires. This will pseudonymise the participant's details and information, ensuring continuity of the participant's data through the data collection and analysis.

Data free from personal identifiable data was analysed at the research site or in the lead researcher's home (transferred securely using an encrypted memory device as per Trust policy). Only researchers directly involved in the project had access to participant information.

4.0 RESULTS

4.1 PARTICIPANTS

An expert panel and patient representatives conducted the formative evaluation. The expert panel (n=22) (5 male, 17 female), consisting of ten dietitians, three consultant physicians, six diabetes specialist nurses, one midwife recruited from the Countess of Chester Hospital NHS Foundation Trust and one physical activity specialist and one web designer recruited from private companies specialising in post natal exercise and web design respectively. The patient representatives (n=20) consisted of 8 females with a diagnosis of type 1, type 2 or gestational diabetes and 12 females of childbearing age without such diagnosis. The characteristics of users are shown in table 4.1.

CHARACTERISTIC	Expert group	Patient representatives
Age		
18-24	1	3
25-29	3	6
30-34	2	2
35-39	3	2
40-44	4	5
45-49	7	1
50+	2	1
Education		
Secondary/high school	0	3
A level	1	6
Undergraduate degree	12	9
Masters degree	4	2
Professional degree (MD / PhD etc.)	5	0
Computer skill level		
1 (poor)	0	0
2	1	0
3	5	3
4	14	15
5 (excellent)	2	2
iPad skill level		
1 (poor)	2	2
2	0	1
3	6	3
4	9	11
5 (excellent)	5	3

Table 4.1 Participant characteristics

Measure		**Introduction** Mean (SD)	**Health** Mean (SD)	**Diet** Mean (SD)	**Lifestyle** Mean (SD)	**Baby Health** Mean (SD)	**Living post GDM** Mean (SD)	**Warning signs** Mean (SD)	**Overall** Mean (SD)
Relevance									3.56 (0.51)
1. I feel that the content of the **[x] module** is relevant to a patient with a history of gestational diabetes	Expert group	3.62 (0.5)	3.59 (0.5)	3.67 (0.48)	3.55 (0.51)	3.57 (0.51)	3.68 (0.48)	3.65 (0.49)	3.62 (0.49)
	Patient representatives	3.4 (0.5)	3.3 (0.47)	3.5 (0.61)	3.5 (0.51)	3.47 (0.51)	3.61 (0.61)	3.68 (0.48)	3.49 (0.53)
Usability									3.57 (0.51)
2. The **[x] module** of the multimedia education program is easy to use 3. The **[x] module** of the multimedia education program is easy to orientate	Expert group	3.74 (0.45)	3.64 (0.49)	3.5 (0.59)	3.5 (0.55)	3.62 (0.49)	3.53 (0.5)	3.63 (0.49)	3.59 (0.51)
	Patient representatives	3.3 (0.46)	3.68 (0.47)	3.63 (0.49)	3.42 (0.55)	3.63 (0.49)	3.57 (0.5)	3.61 (0.5)	3.55 (0.49)
Content									3.34 (0.60)
4. The content of the **[x] module** of the multimedia education program kept me interested throughout 5. The content of the **[x] module** of the multimedia education program is too advanced / too in depth 6. The content of the **[x] module** of the multimedia education program is too basic	Expert group	3.32 (0.69)	3.32 (0.7)	3.32 (0.69)	3.18 (0.69)	3.33 (0.74)	3.29 (0.67)	3.38 (0.64)	3.31 (0.66)
	Patient representatives	3.27 (0.45)	3.27 (0.47)	3.54 (0.5)	3.41 (0.53)	3.39 (0.53)	3.28 (0.66)	3.42 (0.53)	3.37 (0.54)
Appearance									3.43 (0.53)
7. How do you grade the amount of text used in the **[x] module** of the multimedia education program. 8. How do you grade the graphic / animation content of the **[x] module** of the multimedia education program 9. How do you grade the interactivity of the **[x] module** of the multimedia education program 10. How do you grade the overall appearance of **[x] module** of the multimedia education program	Expert group	3.26 (0.54)	3.55 (0.54)	3.60 (0.49)	3.40 (0.52)	3.42 (0.5)	3.37 (0.56)	3.26 (0.47)	3.41 (0.53)
	Patient representatives	3.39 (0.54)	3.45 (0.5)	3.73 (0.45)	3.55 (0.5)	3.44 (0.53)	3.38 (0.58)	3.28 (0.56)	3.46 (0.54)

Table 4.2 Questionnaire results

4.2 MULTIMEDIA PROGRAMME FORMATIVE EVALUATION

The results of the formative evaluation are shown in table 4.2 (page 45).

4.2.1 RELEVANCE

Respondents from the expert and patient representative group were asked to grade how relevant the content of each module was to a patient with a history of gestational diabetes (Figure 4.1).

The overall average score for the relevance across all modules was 3.62 for the expert group and 3.49 for the patient representative group, with an overall average score of 3.56. This indicates that the average score for both groups, across all modules were graded between agree and strongly agree.

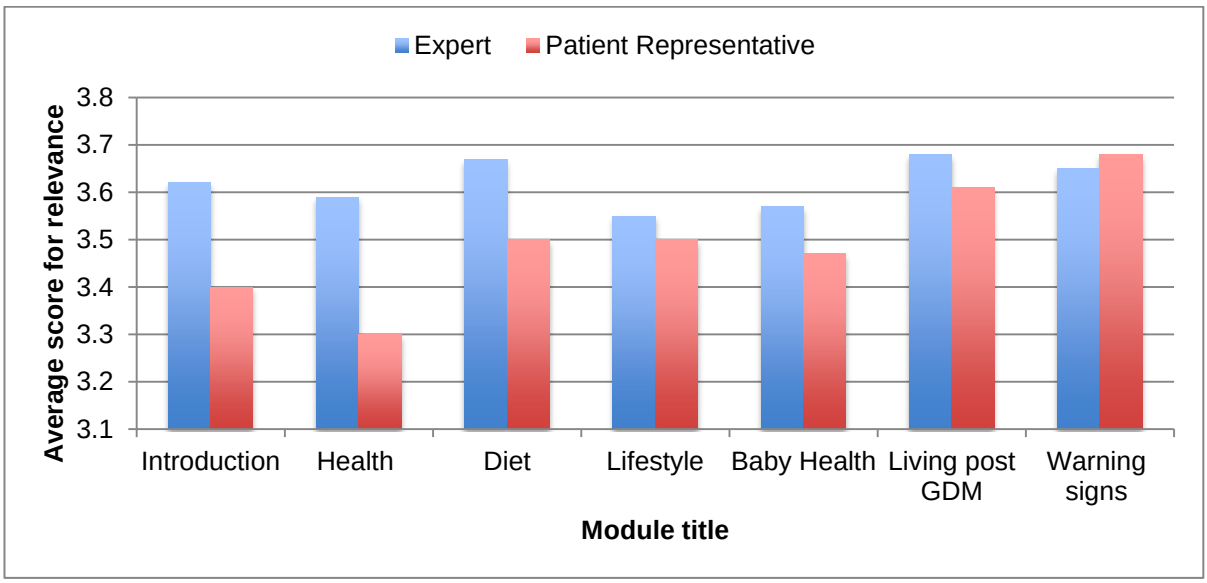

Figure 4.1 – Average score for relevance across programme modules

For the introduction module, patient representative users commented that the animation used was relevant to the patient group and to the content. However, One member from the expert group questioned the relevance of including the video explaining the physiology of diabetes within the health section. Evaluations from both groups mentioned that they enjoyed the video of the

post-natal exercise class showing that exercise is possible and accessible to this population of women and that the suggestions of exercise presented were relevant to new parents. Comments from the expert group mentioned that the baby health module was very relevant and would be interesting and informative to all new mums. Further comments on the living post GDM module mentioned that they felt that the video of the woman who has made lifestyle changes as a result of having a history of gestational diabetes to be relevant and to show realistic steps and ideas to cope after GDM. For the warning signs module, the expert group commented that the content was very relevant to the patient group and that it effectively alerts the patients to symptoms to watch out for and encourages them to act.

4.2.2 USABILITY

Respondents from the expert and patient representative groups were asked to grade the usability of each module of the programme through questions relating to how easy the module was to use and how easy the module was to orientate (Figure 4.2). The average score across all modules was 3.59 and 3.55 for the expert and patient representative groups respectively, with an overall average score of 3.57. This indicates that the average score for both groups, across all modules were graded between agree and strongly agree.

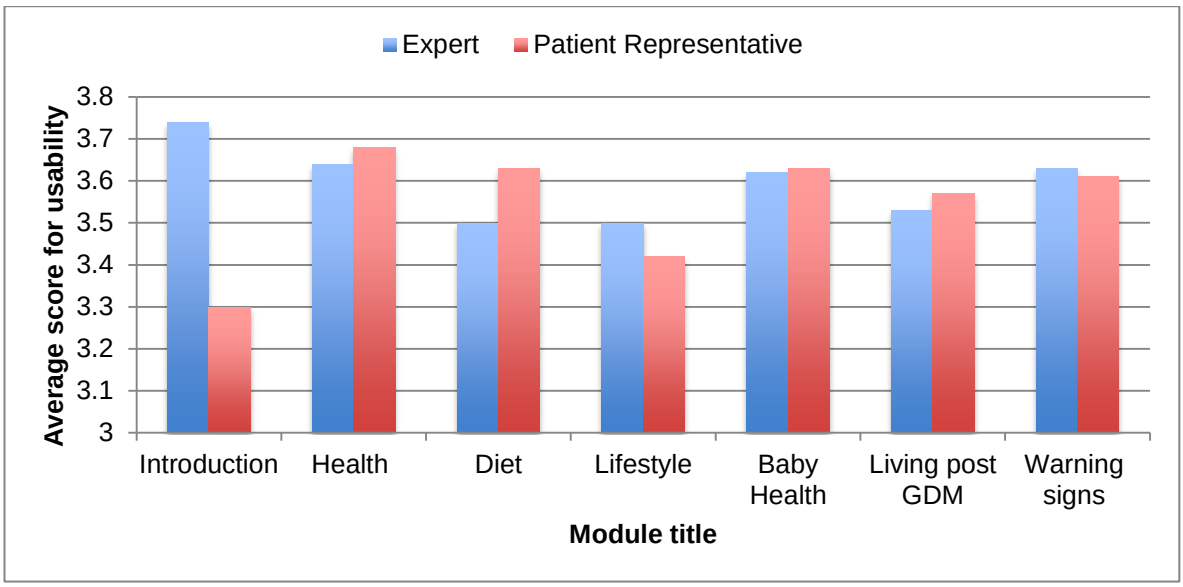

Figure 4.2 Average score for usability across programme modules

For the introduction module, both expert and patient users commented extensively that they felt that the module was simple, clear and easy to navigate. It was mentioned by members of both groups that it would be useful to be able to navigate back to this section from the main screen. For the health module, patient representatives commented that it was simple to use, while an expert group member suggested that the video showing the physiology of diabetes should be moved from 'healthy weight' to it's own section. Both groups commented that the click and drag function present within the games in the diet section was occasionally hard to use and also that the games and quiz needed further explanation of what to do. Comments from both groups mentioned that they found navigation through the lifestyle section challenging. For the baby health module, patient representative users commented that the module was easy to access and the expert users went on to comment that both the baby health and the warning signs modules were straightforward, clear and easy to use.

4.2.3 CONTENT

Expert and patient representative users were asked to grade the content of each module by answering whether the module kept them interested throughout, was too advanced/ in depth or too basic (Figure 4.3). Results from the questionnaire showed that the average score across all modules was 3.31 and 3.37 for expert and patient representative groups respectively, with an overall average score of 3.34. This indicates that the average score for both groups, across all modules were graded between agree and strongly agree.

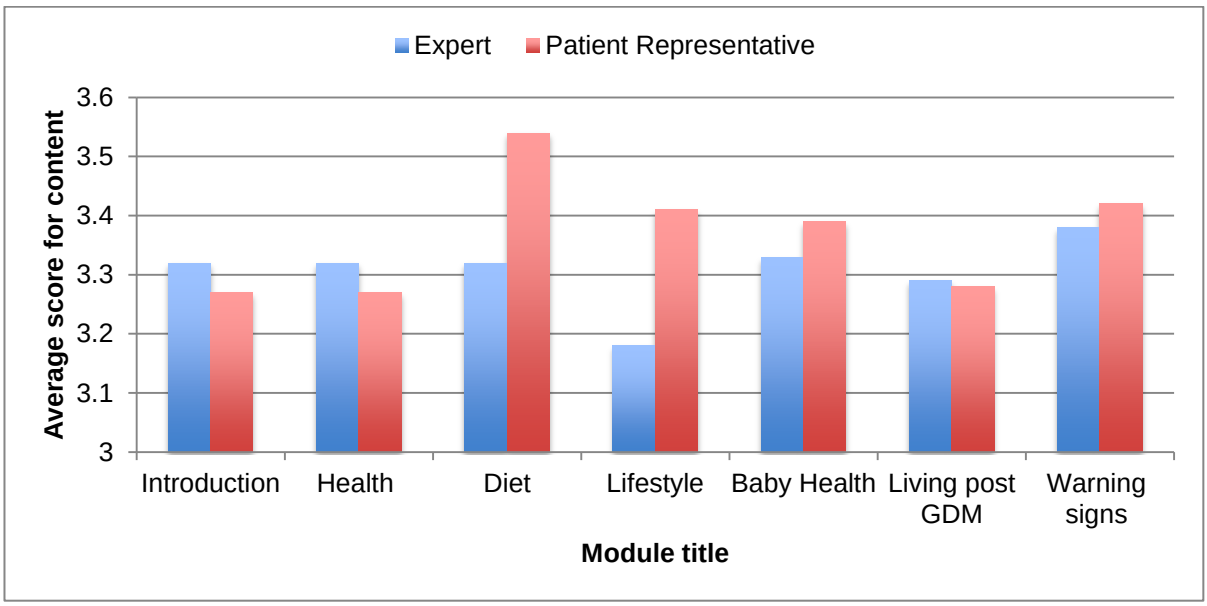

Figure 4.3 Average score for content across programme modules

For the introduction module, comments from expert users included that the information was concise and easy to understand, while patient representatives went on to comment that they found the module content informative. Suggestions were made to add information on complications of type 2 diabetes and more information on gestational diabetes.

For the health module, members from both the expert and patient representative groups commented that they enjoyed the video explaining the physiology of diabetes and found the content informative. Expert users commented that they felt the module used appropriate language for the target population and was easy to understand, however a few expert respondents felt that patients may find the information in the video too complicated. This was echoed by some members of the patient representative group, who found the video too long and complex and suggested it would be better if it were more focused on gestational diabetes.

Many members of both groups stated that they particularly enjoyed the games and quiz within the diet section. Expert group members commented that they found the content interesting, informative and gave the opportunity to test their knowledge, while patient representative users commented that they particularly enjoyed the top tips, the meal examples and the portion sizes mentioned. Users suggested mentioning the recommended number of portions, per food group, per day. It is also noted that inadequate information was provided on portion size on the 100kcal game and coffee shop quiz question.

For the lifestyle module, users from both groups commented that they enjoyed the use of the videos of the midwives and postnatal exercise class within the lifestyle module. Expert users commented that they found the content clear and enjoyed the exercise options suggested for the target population. Both groups liked the balance scale activity showing the length of exercise required to burn off a specific number of calories. Patient representative users liked the use of real mums and commented that it made the advice seem more friendly, realistic

and manageable. It was noted by some in both groups that it would be useful to have longer to read the text between the different sections in the video and some noticed some repetition in the midwives video.

In the baby health section, both groups of users found the content informative. Expert users commented that they particularly enjoyed the weaning advice and the quiz and found the content of the module factual, thorough and easy to understand. Patient representative users mentioned that they particularly enjoyed the future health section and found the table format of the module easy to understand. They also commented that they found the content practical and helpful.

For the living post GDM module, users from both groups commented that they particularly enjoyed the personal account of dealing with lifestyle changes following GDM and that this made the advice more relatable for them. However, it was also noted by members of both groups that they felt that the video was too long and some felt bored by it. Some also noticed that the patient in the video was looking at notes during the filming, which made it feel less believable to them.

In the warning signs section, members of both groups commented that they felt that the content represented a good summary of the objectives for the programme, was clear and easy to understand. However, some users felt that the repetition was unnecessary, as this information had been covered within the health section.

4.2.4 APPEARANCE

Expert and patient representative users were asked to grade the appearance of each module through answering questions relating to the amount of text used, the graphic/animation content, the interactivity and the overall appearance (Figure 4.4). Results from the questionnaire showed that the average score across all modules was 3.41 and 3.46 for expert and patient representative groups respectively, with an overall average score of 3.43. This indicates that the average score for both groups, across all modules were graded between good and very good.

Comments from both groups of users on all modules mentioned that it would be beneficial to have larger text to make the content easier to read.

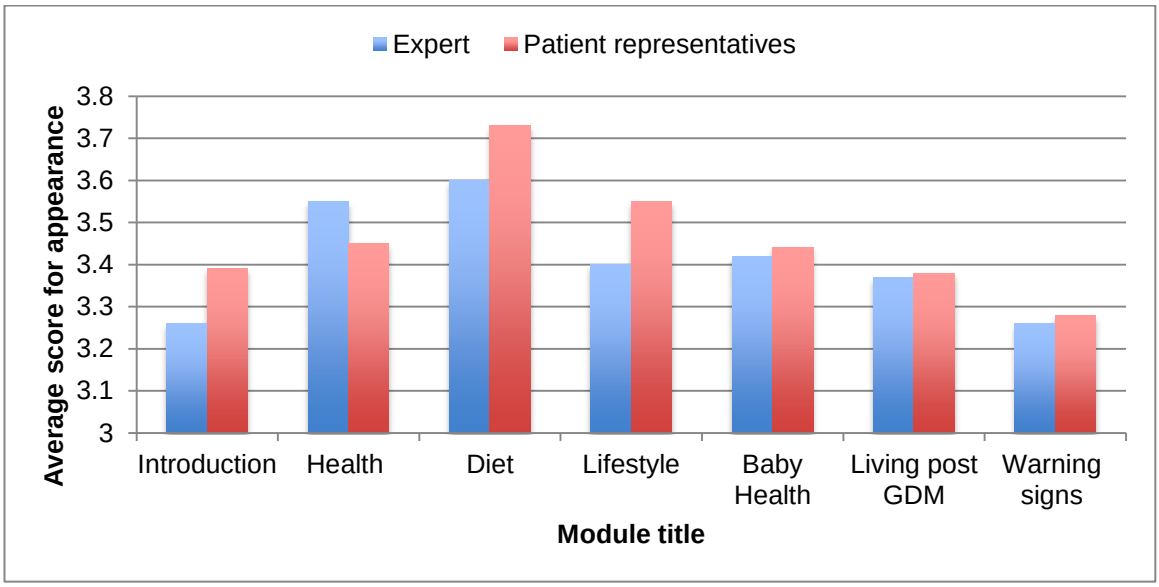

Figure 4.4 Average score for appearance across programme modules

In the introduction module, both groups of users commented that they liked the use of bright colours, enjoyed the use of graphics and thought that there was an appropriate amount of text used. Users from both groups commented that they liked the use of pictures in the health module. Members of the expert group

went on to comment that they found the graphics and animation clear, that they supported the information well and that there was a good balance of text, pictures and video. Large numbers of both groups commented that they particularly enjoyed the interactive components of the diet module. Members of the expert group also commented that they liked the overall appearance and graphic content of the module, but would have liked the size of the pictures to be bigger and less text displayed. For the lifestyle module, users commented that they liked the use of the video and that there was not too much text to read. Users in both groups liked the use of pictures in the baby health module and patient representative users went on to comment that they found the table format easy to follow, but that it would benefit from being bigger to make it easier to read. They also commented that there was a large amount of information in the voice over of the 'foods to avoid' section, which may benefit from additional animation to keep users engaged. For the life after GDM section, both groups of users commented that they liked the option to read the script of the video, although members of the expert group felt it would benefit from additional interactivity to keep users interested. Expert and patient representative users commented on the excellent presentation of information, bright colours and felt that it drew attention to the important points within the warning signs module.

5.0 DISCUSSION

This paper reports on the development process and formative evaluation of a tablet based multimedia programme 'Keeping Healthy after Gestational Diabetes'. The aim of the programme was to support women with a recent history of gestational diabetes to make lifestyle changes with the view to reducing the risk of type 2 diabetes in the future. The objective of this stage of the project was to evaluate the relevance, usability, content and appearance of the programme and also to identify any issues with the programme prior to proceeding to clinical trial. Overall, findings from the formative evaluation suggest that users found the programme relevant, easy to use, interesting and visually appealing, suggesting that this may be a feasible and acceptable mode of education.

Lifestyle interventions that combine changes in diet and exercise, such as those employed in the DPP trial have been found to be effective in reducing the risk of type 2 diabetes in high-risk groups (Knowler et al., 2002), such as those with a history of GDM (Ratner et al., 2008). However, as the women recruited had their first GDM complicated pregnancy an average of 12 years previously, this limits the generalisability of these results to women in the postpartum period, who may face considerably different barriers to behaviour change and may require a different method of education. Indeed, postpartum women cite multiple barriers to attending education and engaging in health behaviour change (Nicklas et al., 2011; Swan, Kilmartin & Liaw, 2007). Furthermore, focus group studies in women with a history of gestational diabetes have indicated that an Internet or multimedia based education programme, which they could

access in their own time, would be favourable above face-to-face appointments (Nicklas et al., 2011). NICE Technical Appraisal 60 recommends that education sessions should be accessible to the broadest range of people and use a variety of techniques to promote active learning, adapted to meet the needs of the population (NICE, 2003). The reason for developing the programme was due to the challenges faced engaging this population of women in patient education at the Countess of Chester Hospital NHS Foundation Trust. Group education sessions were poorly attended and time pressures meant that offering individual education appointments with clinicians was unsustainable. By providing education through a multimedia programme it may more effectively meet the needs of the population. Given the widespread use of computer technology, multimedia education may more effectively meet the needs of this population and offers a unique opportunity to engage this young, mobile population with technology (Nicklas et al., 2011).

To our knowledge, this is the first tablet-based multimedia education programme aimed at women with a history of gestational diabetes that includes a detailed description of the development and formative evaluation process. Nicklas et al. (2014) evaluated the efficacy of a web-based lifestyle intervention in this population group and showed the potential for success, however did not describe the development or formative evaluation of the programme. Evaluation of patient education in any form is essential in order to ensure their efficacy, patient safety and to maintain high standards of patient care (Robinson, Patrick, Eng & Gustafson, 1998). In particular, it is important to evaluate computer-based education, as poorly designed programmes, containing inaccurate, inappropriate or out-of-date information can have

potentially detrimental effects, may lead to poorer outcomes and may delay the patient seeking expert opinion (Robinson, Patrick, Eng & Gustafson, 1998; Henderson et al., 1999). Formative evaluation takes place before the implementation of a final product, which influences its further development (Preece et al., 1994). It also reduces the need for further revisions after implementation requiring additional time and resources and increases the chance of the programme meeting the goals intended (Jones et al., 2004). The Department of Health advises patients to be involved in the formative evaluation stage in any research which affects patient care in the UK (Department of Health, 2001). Despite this, few published studies report on the development and formative evaluation of multimedia patient education programmes.

5.1 PARTICIPANT CHARACTERISTICS

Participants recruited represented a wide range of ages and educational attainment in both the expert and patient representative groups. The age of the expert group was on average older, with a median age group of 40-44 years compared to 30-34 years in the patient representative group. Both had highest numbers of people being educated to undergraduate level however the expert group had five people achieving professional degrees compared to none in the patient representative group. Computer and iPad skill level were similar in both expert and patient representative groups with the majority rating themselves highly in both.

While past research suggests that the use of computers and technology in the target population is high (Nicklas et al., 2011), it is possible that this mode of education may not be acceptable to all patients within this population.

Participants were recruited from the Cheshire area, which is a relatively affluent area with less social deprivation compared to other regions of the UK (West Cheshire CCG, 2014), which may explain the relatively high educational attainment in the patient representative group. This may therefore limit the generalisability of the results of this study. Furthermore, participants in the patient representative group were self-selected individuals, which may be a limiting factor in these results as these individuals may be more likely to be motivated to complete the education.

5.2 ACCEPTABILITY

"Keeping Healthy after Gestational Diabetes" was deemed as acceptable based on the results of the MEPPA – evaluation of a prototype tool, which measured relevance, content, usability and appearance. Acceptability is defined as how users may perceive the programme as suitable, through measures of appropriateness or participant satisfaction (Bowen et al., 2009). Acceptability has been assessed in other studies through the use of web–tracking programmes, such as Google analytics [Google, Mountain View, CA, USA] (Gray, 2014). This feature is an advantage of a web-based platform, as it allows detailed information on which sections of the programme have been accessed, and how often. According to Bowen et al. (2009), feasibility can be measured by establishing if there is demand; how much a programme is likely to be used. At the formative evaluation stage it is not possible to establish this measure, but it is proposed that the high ratings of relevance, content, usability and appearance achieved, and the suggestions for improvement collected from

this phase of the study will increase the chance of feasibility when introduced to formal users in the next phase of testing.

Relevance is defined as “The ability to retrieve information that satisfies the needs of the user” (Merriam-Webster dictionary). Scores on the MEPPA – evaluation of a prototype tool in relation to the relevance of the programme were positive, with an average score of 3.56, with at least 95% of users rating either agree or strongly agree to the statement “I feel that the content of [x] module is relevant to a patient with a history of gestational diabetes. Results show that the expert group rated every module as more relevant than the patient representative group, except for the warning signs module. This is in contrast to previous research in heart failure, which has found that healthcare professionals tend to rate information as less relevant than patients in most areas (Stromberg et al., 2002). The disparity in the findings in this study, however, may be due to the use of patient representatives, rather than formal users i.e. women with a history of gestational diabetes.

Usability can be defined as ”the extent to which a product can be used by specified users to achieve specific goals with effectiveness, efficiency and satisfaction in a specified context of use” (ISO 9241, 1998). Scores on the MEPPA – evaluation of a prototype tool in relation to the usability of the programme were positive, with an average score of 3.52, with at least 95% of users rating agree or strongly agree to the statements “the [x] module of the multimedia education programme was easy to use” and “the [x] module of the multimedia programme was easy to orientate” for each module. The lowest

scores achieved are from the introduction and lifestyle section, where users reported navigation issues, which will be reviewed prior to clinical trial.

Content is defined as “The topics or matter treated in a written work” (Merriam-Webster dictionary). Scores on the MEPPA – evaluation of a prototype tool in relation to the content of the programme were positive, with an average score of 3.52, with at least 90% of users rating agree or strongly agree to the statements which referenced whether the programme kept users interested throughout a module and whether it was pitched at the right level; neither too basic, nor too advanced. Patient representatives rated the diet, lifestyle and baby health modules highly and commented that they particularly enjoyed the interactive elements, such as the games and quizzes. The large number of evaluations per module achieved in this formative evaluation increases the validity of the content.

Appearance is defined as “all visual attributes of a substance or object” (ISO 5492, 2008). Scores on the MEPPA – evaluation of a prototype tool in relation to the appearance of the programme were positive, with an average score of 3.43, with at least 94% of users rating agree or strongly agree to the statements relating to the amount of text used, the animation / graphics used, the interactivity and the overall appearance of the modules. Users from the patient representative group consistently rated the appearance as higher than the expert group in all modules except from the health module.

These results provide preliminary evidence that the tablet based multimedia programme “Keeping Healthy after Gestational Diabetes” is acceptable, based

on measures of relevance, content, usability and appearance, assessed by expert group members and patient representatives.

5.3 COMPARISON WITH EXISTING LITERATURE

One must consider the change in motivation for behaviour change from pregnancy to the postpartum period. During a pregnancy complicated by gestational diabetes, NICE recommends monitoring by a diabetes team from diagnosis to birth of the baby, requiring adaptations to diet and exercise, possible pharmacological intervention and intervention during labour (NICE,2015). The motivation for behaviour change at this time point is focused on reducing the risk of adverse pregnancy outcomes, such as macrosomia, trauma during birth, caesarean section and perinatal death (Nicklas et al., 2011). In contrast, following gestational diabetes the motivation for behaviour change is different. In the majority of cases, hyperglycaemia does not persist following birth (Di Cianni et al., 2010) and therefore the immediate risk for mother and baby subsides and while many women may recognise that gestational diabetes poses a risk for future type 2 diabetes, few women rate themselves at high risk (Kim et al., 2007), and therefore more immediate issues may take priority, such as learning the skills to provide care for their baby and managing changing sleep patterns. Indeed, women with a history of gestational diabetes have been found no more likely to engage in health behaviour change in the period shortly following birth than women following a normoglycaemic pregnancy (Bennett et al., 2013; Kieffer, Sinco & Kim, 2006).

Previous findings of lifestyle intervention studies implemented within the postpartum period remain controversial, with several methodological limitations,

including small sample sizes (Leermakers, Anglin & Wing, 1998), lack of efficacy (Ostbye et al., 2009) and high attrition rates (O'Toole, Sawicki & Artal, 2008; Kim et al., 2012). It was postulated that this may be due to the myriad barriers presented to women in the early postpartum stage (Nicklas et al., 2011) and that a multimedia programme may overcome some of these barriers and may be a more suitable form of education. Despite the limited evidence and significant barriers cited in this area, the results yielded from a randomised controlled trial conducted by Nicklas et al. (2014) provide promising results for the efficacy of a web-based lifestyle intervention programme in women with a history of gestational diabetes. Participants were recruited at 6 weeks postpartum and were followed up for 12 months, providing a unique insight into the efficacy of lifestyle intervention in the early postpartum period in this population using a web-based platform. The content of the web-based programme was based on the DPP trial (Knowler et al., 2002) and the goal of the programme was to return to pre-pregnancy weight over the study period. They found that women in the intervention group lost significantly more weight compared to the control group, with the intervention group losing an average of 2.8kg at 12 months postpartum compared to baseline, compared to the control group who still remained an average of 0.5kg above baseline weight. These results are promising and provide evidence that a web-based lifestyle intervention may be effective, potentially overcoming some of the barriers presented to education in this population. However, one must consider the additional resources that women in this trial received, such as access to a lifestyle coach, free gym membership and laptop computers which may limit the financial viability for such an intervention to be scaled up and implemented in routine clinical care.

In contrast to this, Kim et al. (2012), implemented a web-based pedometer intervention in 49 women with a history of gestational diabetes. They created a 13 week web based education programme, including a pedometer programme which tracked progress with the primary outcome of improving blood glucose levels between baseline and follow up and secondary aims to measure self-efficacy, risk perception and physical activity levels. The intervention, however, was unsuccessful and the intervention failed to have an impact on blood glucose levels or any behavioural constructs, particularly physical activity. The study had several methodological limitations, including a small sample size, short follow up time and failure to design the programme to suit the users needs (Kim et al., 2012).

There are several factors that may have influenced the varying success of these web-based programmes in this population. For example, Nicklas et al. (2014) addressed both physical activity and diet within their lifestyle intervention, compared to just physical activity in Kim et al. (2012). Nicklas et al. (2014) reported no change in physical activity levels between intervention and control groups, while achieving a significant reduction in calorie intake in the intervention group compared to the control group. Indeed, other studies have also reported that lifestyle interventions targeted at increasing physical activity in postpartum women were not effective (Ostbye et al., 2009; Hu et al., 2012; Gray, 2014). This finding may suggest that the elements encouraging dietary modification, or a combination of both diet and physical activity, may be more effective than physical activity alone in yielding results.

Furthermore, the additional support supplied in Nicklas et al. (2014), such as the access to the lifestyle coach may be an important factor to success. Within this study it is challenging to separate the effect of the multimedia programme and the lifestyle coach, though other studies have shown that a computer based programme is equally, or more effective in promoting behaviour change (Fox, 2009; Evans, Edmondson-Drane & Harris, 2000; Marsch & Bicket, 2004; Jenny & Fai, 2001; Keulers et al., 2007). This highlights the importance of how a multimedia programme is integrated into clinical care. It is not the intention for this multimedia programme to replace the need for contact with a clinician, however, if designed and implemented correctly, may serve to compliment existing care.

It is also important to consider the point at which education is offered in relation to the illness course. Evidence has shown that the risk of type 2 diabetes persists for a number of years, increasing most steeply in the first 5 years postpartum (Kim et al., 2002). While the optimal time for lifestyle intervention is likely to differ for individual women according to their circumstances, providing education from an early stage may increase knowledge, self-efficacy and motivation to progress through the behaviour change cycle within the health belief model (Becker, 1976) and help to prepare for behaviour change at a later stage. Multimedia education holds the advantage that women are able to repeat modules at a later date, when they may feel more able to make the lifestyle changes.

5.4 ADVANTAGES OF THE MULTIMEDIA PROGRAMME

Findings of the study suggest that users were satisfied with the multimedia programme 'Keeping Healthy after Gestational Diabetes'. A strength of this multimedia programme is that the contents were evaluated by both expert and patient representatives in this study and were based on clinical expertise and literature (NICE, 2015; NICE, 2012; Knowler, 2002). The large number of evaluations per module using both experts and patient representatives increases the validity of the content. Indeed, Virzi (1992) conducted a study examining the number of evaluations required to test usability and concluded that 80% of usability problems are detected with five evaluations per module.

Multimedia education has the advantage of appealing to a wide range of learning styles. Evidence has shown that the combination words, pictures, animation, voice-overs and videos used in multimedia programmes employ both channels of working memory (eyes and ears), which has been found to significantly increase learning capacity (Mas, Plas, Kane & Papenfuss, 2003; Paas & Sweller, 2014). Further to this, multimedia programmes contain higher amounts of interactive learning compared to other education methods such as leaflets or videos, moreover, the use of tablet computers incorporating touchscreen technology, increases interactivity further. Previous studies have found that education that incorporates interactive learning is more effective than traditional teaching methods (Consoli, Said, Jean, Menard, Plouin & Chatellier, 1995). Indeed, users commented that they particularly enjoyed the elements with higher levels of interactivity, such as the games and the quizzes within the programme. As well as interactivity, the games and quizzes create direct

feedback and repetition of key learning points from the module to support the learning process.

Another advantage of the programme is that it is split up into modules, each on a different topic and taking 10-15 minutes to complete, which users are free to complete in any order. This feature is consistent with the constructivist learning theory, which states that knowledge is achieved when new information is integrated into existing knowledge (Mayer & Moreno, 2002). Furthermore, on a practical level, as the target audience are new mothers, the modular format allows them to take regular breaks to care for their new babies.

Previous studies have shown that patients with low literacy skills benefit most from individualised, self-paced learning such as that provided by multimedia education (Jones, Nyhof-Young, Friedman & Catton, 2000). This is an important consideration when delivering patient education for women with a history of gestational diabetes as this population are often from lower socioeconomic backgrounds (Kim, Sinco, Keiffer, 2007). Patient representatives assessed in this study had a relatively high educational attainment level; it would be interesting to evaluate the efficacy of the programme in a less affluent area, with lower educational ability and literacy levels. The advantage of a multimedia platform is that users are able to repeat modules; indeed Huss, Salerno & Huss (1991) found that a repeated computer education session was more effective at creating behaviour change than a single face-to-face session with a clinician in patients with atopic asthma. Following summative evaluation of the programme, it is proposed that the programme will be available to use in clinical settings and also be made

available for use through the hospital's website so that users can access it from home and can repeat modules at their leisure.

Users commented that they particularly liked the videos of the postnatal exercise session, the midwives giving exercise advice and the lady in the 'Living post GDM' video. They commented that they liked the use of real mums and healthcare professionals who they could relate to as it made the advice more relevant and realistic to them. Establishing relevance is an important part of creating a learning context and encouraging users to construct understanding. Through establishing personal and real-world relevance of new information, users are more able to relate the information to the world around them and organise it into their own set of beliefs (Kember, Ho & Hong, 2008).

5.4 SUGGESTIONS FOR IMPROVEMENT

The majority of users were very positive about 'Keeping Healthy after Gestational Diabetes' multimedia programme, only a few suggestions for improvements were made. One criticism reported by an expert group member was that they did not feel it was relevant to include a video explaining the physiology of diabetes within the health section and felt it was too complicated for the target audience. The aim of the video was to explain how making lifestyle changes could reduce the risk of type 2 diabetes. The video included a commentary of carbohydrate metabolism in normal, type 1 and type 2 diabetes models. It is accepted that including information on the physiology of type 1 diabetes is not relevant to the aim of the programme, however due to financial constraints it was not possible to develop a video of such high quality specifically for the programme and were therefore restricted to the choice of

existing evidence based, reputable videos. On reflection, it may have been better to create a more basic, lower quality animation and ensure all of the content was relevant to the aim of the programme.

Further to this, another user felt that the programme should include more information on the complications associated with type 2 diabetes and further information on the physiology of gestational diabetes. As the objective of the programme was to inform women with a history of gestational diabetes of lifestyle changes necessary in order to reduce the risk of type 2 diabetes in the future, it was felt that these topics extended beyond the scope of the programme. Further user comments which require minor alterations include the addition of further explanation on how to play the games and quiz in the diet section, increasing the time to read questions within the midwife video in the lifestyle section, increasing the size of the text throughout the programme and moving the video in the Health section from 'Healthy Weight' to its own 'Video' section.

Suggestions to improve the usability of the programme included adding a module link button on the home screen to return to the introduction section and reviewing the navigation at the end of the lifestyle section. These issues will be addressed with the support of a web developer prior to formal evaluation. Despite receiving high ratings for usability, comments from users highlighted some areas that required modification within the diet section. For example, one of the games required users to click and drag a variety of food products into correct food group boxes, however once the image was in a box it was difficult to drag it out again. Further comments from users stated that it would be useful

to have a ‘reveal’ button in the games, to show the correct answers. These issues will be reviewed and resolved prior to formal evaluation.

A further option was to develop the multimedia programme using an Apple iOS platform, which would allow users to download the app to their iPhone or iPad. However, it was felt that an HTML based programme would allow greater flexibility and accessibility to users. This is because an HTML platform allows the programme to function on any device, without bias towards a particular technology, whereas an Apple iOS platform will only function on Apple devices. While an HTML platform does not allow individual users to download the programme to their device, they are able to access the programme through a web version, which is optimised for use with touchscreen devices such as smart phones and tablets. Furthermore, an iOS app requires updating frequently in line with most recent iOS version and is significantly more expensive to develop and maintain.

5.5 STUDY LIMITATIONS

There are several limitations to this study that should be taken into account when interpreting the results. There may have been potential for response bias during the evaluation. Users may have provided more favourable feedback about the programme when faced with a member of the research team. Due to limitations in staff numbers it was not possible to eliminate this bias, but it was minimised by not informing the user of researcher involvement and allowing the user to work through the programme and questionnaire by themselves.

Other methodological issues that may limit the validity of the results include the failure to include formal users, i.e. women with a history of gestational diabetes, in the development or formative evaluation stage. Formal users will be used in the next stage of evaluation, where the efficacy of the programme will be assessed. This will measure knowledge, self-efficacy and risk perception and will also assess the overall acceptability of the programme and mode of education to this patient group before releasing the programme for use in clinical practice.

There are also limitations with the questionnaire used to evaluate the programme. As, to our knowledge, only one other study has reported on the use of a multimedia programme for women with a history of gestational diabetes (Nicklas et al., 2014) and they did not report on the development or formative evaluation process, the MEPPA – evaluation of a prototype questionnaire was developed to meet the needs of this study. It has been adapted from Ronning et al. (2013) study, where it was used to evaluate a multimedia programme for patients with congenitally malformed hearts and adapted to be appropriate for use with a programme targeted towards women with a history of gestational diabetes. It has therefore not been used in this patient group before. Furthermore, Ronning et al. (2013) did not comment on the internal consistency or validity of the questionnaire. As a result, further studies are required to analyse the validity and reliability of this instrument. Another potential method of data collection for this study could have been qualitative interviews, which would have allowed for follow up questions. However this method is much more time consuming both to conduct and to transcribe and analyse the results.

Due to financial constraints, the design of the multimedia programme meant that it was not possible to analyse results from the quizzes, which were used within the diet and baby health modules. The quizzes were primarily used to act as a form of self-test and to allow repetition of key learning outcomes, however hold the potential to gather data if further development of the programme was to take place.

6.0 CONCLUSIONS AND CLINICAL IMPLICATIONS

Results from this initial formative evaluation determined that 'Keeping Healthy after Gestational Diabetes' multimedia education programme was relevant, easy to use, interesting and visually appealing. The results of this evaluation will be used to make alterations to the programme to create a final product to conduct a future summative evaluation to formally evaluate the efficacy and acceptability of the programme with formal users.

Evidence has shown the potential efficacy of lifestyle intervention to prevent or delay the onset of type 2 diabetes in high-risk groups, such as those with a history of gestational diabetes (Ratner et al., 2008). However, women cite multiple barriers to attending to education sessions and engaging in health behaviour change (Nicklas et al., 2011; Swan, Kilmartin & Liaw, 2007). Given the widespread use of computer technology, multimedia education offers a unique opportunity to engage this young, mobile population with technology (Nicklas et al., 2011). The evolution of computer technology has resulted in a huge increase in multimedia patient education programmes, which have the potential to improve health outcomes in a wide range of conditions (Fox, 2009). The current study provided a detailed description of the development and initial formative evaluation of an innovative tablet based multimedia education programme targeted towards encouraging health behaviour change in women with a history of gestational diabetes. 'Keeping Healthy after Gestational Diabetes' is aimed towards increasing knowledge and self-efficacy in patients towards making positive health behaviour change to reduce the risk of developing type 2 diabetes in the future. The programme was developed

through collaboration of multidisciplinary healthcare providers, patient representatives and software programme developers. Expert and patient representative user feedback and suggestions for improvement have been summarised and will be used to make alterations to the programme to create a final product.

If the summative evaluation is successful, the programme has the potential to be a useful tool to complement the care given to women following gestational diabetes. While multimedia education will never be a replacement for face-to-face contact with a clinician, evidence suggests that it may be possible to educate patients using this method, while maintaining patient satisfaction (Keulers, Welters, Spauwen & Houpt, 2007). If the patient education can be delivered through a multimedia programme, it may allow more time in consultations for patients to ask questions and discuss lifestyle goals. The discussion between clinician and patient is more likely to be at an equal level, increasing the chance of shared decision making.

Furthermore, As evidence has shown that well-made, evaluated multimedia programmes may be more effective than traditional education and with the current climate of healthcare reform, where the priority lies in cost-effective delivery of high quality services, multimedia programmes are likely to become commonplace in patient education. Areas for future research include comparing the efficacy of the multimedia programme to other forms of education and analysing the longer-term implications of the education on knowledge retention and health behaviour change.

7.0 REFERENCES

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APPENDIX 1: ETHICAL APPROVAL

Part of the research infrastructure for Wales funded by the National Institute for Social Care and Health Research, Welsh Government.
Yn rhan o seilwaith ymchwil Cymru a ariannir gan y Sefydliad Cenedlaethol ar gyfer Ymchwil Gofal Cymdeithasol ac Iechyd, Llywodraeth Cymru

Wales REC 4
G1/G2 Croesnewydd Hall
Croesnewydd Road
Wrexham Technology Park
Wrexham LL13 7YP

Telephone : 01978 726377

E-mail : tracy.biggs@wales.nhs.uk

Website : www.nres.nhs.uk

31 October 2014

Miss Helen Jacobs
28 Rhuddlan Court
Saltney
Chester
CH4 8NH

Dear Miss Jacobs

Study title:	**A multimedia approach to diabetes structured education: The effects of "Keeping Healthy After Gestational Diabetes" on patient knowledge, self-efficacy and acceptability of a multimedia based education program.**
REC reference:	**14/WA/1169**
IRAS project ID:	**140757**

Thank you for your letter of 28 October 2014, responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information was considered by a Sub-Committee of the REC at a meeting held on 31 October 2014. A list of the Sub-Committee members is attached.

We plan to publish your research summary wording for the above study on the HRA website, together with your contact details. Publication will be no earlier than three months from the date of this opinion letter. Should you wish to provide a substitute contact point, require further information, or wish to make a request to postpone publication, please contact the REC Manager, Mrs Tracy Biggs, Tracy.Biggs@Wales.nhs.uk.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the study.

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission ("R&D approval") should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements.

Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at http://www.rdforum.nhs.uk.

Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of approvals from host organisations

Registration of Clinical Trials

All clinical trials (defined as the first four categories on the IRAS filter page) must be registered on a publically accessible database within 6 weeks of recruitment of the first participant (for medical device studies, within the timeline determined by the current registration and publication trees).

There is no requirement to separately notify the REC but you should do so at the earliest opportunity e.g. when submitting an amendment. We will audit the registration details as part of the annual progress reporting process.

To ensure transparency in research, we strongly recommend that all research is registered but for non clinical trials this is not currently mandatory.

If a sponsor wishes to contest the need for registration they should contact Catherine Blewett (catherineblewett@nhs.net), the HRA does not, however, expect exceptions to be made. Guidance on where to register is provided within IRAS.

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Ethical review of research sites

NHS sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Non-NHS sites

Approved documents

*The final list of documents reviewed and approved by the Committee is as follows:

Document	*Version*	*Date*
Covering letter on headed paper [Countess of Chester Hospital are acting as sponsor]	email	22 September 2014
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [UOC indemnity]	1	02 July 2014
GP/consultant information sheets or letters [GP letter]	1	02 July 2014
IRAS Checklist XML [Checklist_18092014]		18 September 2014
IRAS Checklist XML [Checklist_28102014]		28 October 2014
Letter from funder [letter from novo nordisk]	1	06 June 2014
Letter from statistician [stats letter]	1	07 August 2014
Letters of invitation to participant [invitation letter]	2	14 October 2014 *
Non-validated questionnaire [MEPPA]	1	02 July 2014
Non-validated questionnaire [Evaluation of Prototype by Patient Representatives]	1	02 July 2014

Non-validated questionnaire [Evaluation of Prototype by Multidisciplinary Team]	1	02 July 2014
Non-validated questionnaire [demographics and clinical characteristics]	1	02 July 2014
Non-validated questionnaire [KORSE-GDM]	1	02 July 2014
Other [additional screening]	1	28 October 2014
Other [Content]	1	17 September 2014
Participant consent form [consent form]	1	02 July 2014
Participant consent form [consent form - initial evaluation]	1	02 July 2014
Participant information sheet (PIS) [participant info sheet]	2	14 October 2014 *
REC Application Form [REC_Form_18092014]		18 September 2014
Referee's report or other scientific critique report [CW letter]	1	11 September 2014
Research protocol or project proposal [research protocol]	1	02 July 2014
Summary CV for Chief Investigator (CI) [cv CW]	1	02 July 2014
Summary CV for student [CV HJ]	1	02 July 2014
Summary, synopsis or diagram (flowchart) of protocol in non technical language [research protocol-non technical]	1	02 July 2014

***please note that the version number and date has been taken from the document footer and not the checklist**

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Reporting requirements

The attached document *"After ethical review – guidance for researchers"* gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

The HRA website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website: http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/

HRA Training

We are pleased to welcome researchers and R&D staff at our training days – see details at http://www.hra.nhs.uk/hra-training/

14/WA/1169	Please quote this number on all correspondence

With the Committee's best wishes for the success of this project.

Yours sincerely

T.a. Biggs.

Professor Alex Carson
Chair

E-mail: tracy.biggs@wales.nhs.uk

Enclosures: *List of names and professions of members who were present at the meeting and those who submitted written comments*

"After ethical review – guidance for researchers"

Copy to: *Lead NHS R&D contact/Sponsor contact - Mrs Sheila Williams*

Chief Investigator - Mrs Christine Wolfendale , University of Chester

APPENDIX 2: CONSENT FORM

University of Chester

Countess of Chester Hospital NHS
NHS Foundation Trust

PARTICIPANT CONSENT FORM – Initial Evaluation

Title of Project: Efficacy of a media education program in post gestational diabetes

A multimedia approach to diabetes structured education: The effects of "Keeping Healthy After Gestational Diabetes" on patient knowledge, self-efficacy and acceptability of a multimedia based education program.

Name of Researcher: Helen Jacobs

Please INITIAL box

1. I have had the opportunity to consider the information presented by the lead researcher, to ask questions and to have these answered satisfactorily. ☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my legal rights being affected. ☐
3. I understand that my data will be held on a computer at the hospital. I give my permission for this data to be held on computer by this party. ☐
4. I agree to take part in the above study. ☐

_____	_____	_____
Name of Participant		Date Signature
_____	_____	_____
Name of Person taking consent	Date	Signature

When completed; 1 for participant (copy); 1 for researcher (original); 1 to be kept with hospital notes (copy)

APPENDIX 3: PARTICIPANT INFORMATION SHEET

University of Chester

Countess of Chester Hospital NHS
NHS Foundation Trust

PATIENT INFORMATION SHEET
"Efficacy of a media education programme in post gestational diabetes"

A multimedia approach to diabetes structured education: The effects of "Keeping Healthy After Gestational Diabetes" on patient knowledge, self-efficacy and acceptability of a multimedia based education program.

Initial Evaluation

Thank you for agreeing to help evaluate a new multimedia education programme for women with a history of gestational diabetes. The Diabetes Unit at the Countess of Chester Hospital has developed a brand new multimedia education program targeted specifically on reducing the risk of type 2 diabetes in the future and is known as "Keeping Healthy After Gestational Diabetes". Evaluation of the prototype version is of vital importance as it helps to assess the usability, appearance and content of the programme to highlight any areas for change before it is released.

If you have any questions about the study, please ask the lead researcher. If you are happy to continue please sign the consent form to participate in the study. Following this, please work your way through each module and fill in each section of the questionnaire as you go.

What is the purpose of the study?
It is desirable that people at risk of diabetes have access to education as part of their routine care. Diabetes is a complex condition, which can have numerous health effects on an individual, and gestational diabetes can increase the risk for developing type 2 diabetes later on. The Countess of Chester Hospital NHS Foundation Trust offers gestational diabetes education in the form of a one-off session known as 'Diabetes Essentials: Gestational Diabetes', however currently there is no education offered to women following the birth of their baby.

The purpose of this study is to evaluate whether a new education tool can improve knowledge of diabetes risks and prevention strategies and your confidence in managing lifestyle change.

Do I have to take part?
No. It is up to you to decide whether to take part or not. Participation in the study is voluntary. You are free to withdraw from the study at any time, without giving a reason. Choosing to withdraw from the study will not affect the standard of your routine care.

Has this study been approved?
This study has been reviewed and approved by the Wales REC 4 committee as meeting ethical standards for high quality, safe and ethical research. NHS Research Ethics Commitees (RECs) safeguard the rights, safety, dignity and wellbeing of people participating in research in the NHS.

What are the possible disadvantages and risks of taking part?
There are no identifiable risks in taking part in this study. The only disadvantage is the additional time it will involve and the burden this may cause for you. The researcher will be as flexible as possible in arranging scheduled contacts and appointment times convenient to you.

What are the possible benefits of taking part?
By taking part you will be contributing to the development of the diabetes service at the Countess of Chester Hospital NHS Foundation Trust, which will hopefully help people in a similar position to you.

What if something goes wrong?
In the unlikely event that something goes wrong as a result of taking part in the study, the Countess of Chester Hospital NHS Foundation Trust provides insurance cover and you would retain the same rights of care as any other patient treated in the National Health Service. If you have any concerns or wish to complain about any aspect of the way you have been approached or treated during the course of this study, please contact:

Sheila Williams, Research Manager Countess of Chester Hospital NHS Foundation Trust,
Countess of Chester Health Park, Liverpool Road, Chester, CH2 1UL
Telephone: 01244 365532

Any concerns or complaints can also be submitted to the Countess of Chester Hospital NHS Foundation Trust Patient Advice and Liaison Service (PALS) by contacting 0800 195 1241. Alternatively you can e-mail PALS on cochpals@nhs.net , or write to the PALS Manager, PALS, Countess of Chester Hospital Foundation Trust, Liverpool Road, Chester CH2 1UL.

Will my taking part in the study be kept confidential?
Yes, all information gathered during the research study will be kept confidential. Only people directly involved in the research will have access to details of your participation. The lead researcher will have responsibility for ensuring that all information is kept in a secure manner. Your medical records will not leave the hospital. For the purposes of analysing and presenting the final results, all information will be anonymised so that participants will not be identifiable.

What will happen to the results of the research study?
The results will be used to help evaluate and develop the education provided by the Diabetes Unit at the Countess of Chester Hospital NHS Foundation Trust. They will also be used as part of a Master's level student research project and may be presented at meetings or published in a journal with interest in diabetes.

Who is organising and funding the research?
The Diabetes Research Fund at the Countess of Chester Hospital NHS Foundation Trust and Novo Nordisk are funding this current research.

Who may I contact for further information?
If you have questions or concerns regarding participation in the research, you are encouraged to speak to you GP who can give you an independent opinion on the research.

If you have any question or would like to discuss this research further please contact Helen Jacobs (lead researcher) at the Diabetes Unit, Countess of Chester Hospital NHS Foundation Trust on 01244 363619 or by emailing hjacobs1@nhs.net .

Thank you for taking the time to read this information

APPENDIX 4: DEMOGRAPHICS QUESTIONNAIRE – PATIENT REPRESENTATIVES

Evaluation of Prototype by Patient Representatives

Gender (please tick)

Male	
Female	
Prefer not to disclose	

Age group (please tick)

18-24	
25-29	
30-34	
35-39	
40-44	
45-49	
50+	

Educational attainment (please tick)

Secondary / High school (GCSE or equivalent)	
A level or college equivalent	
Undergraduate degree	
Masters degree	
Professional degree (eg. PhD, MD)	

Skill level

Please rate your overall computer skill level (1=poor, 5=excellent)

1	2	3	4	5
☐	☐	☐	☐	☐

Please rate your overall I Pad skill level (1=poor, 5=excellent)

1	2	3	4	5
☐	☐	☐	☐	☐

APPENDIX 5: DEMOGRAPHICS QUESTIONNAIRE – EXPERT GROUP

Evaluation of Prototype by Multidisciplinary Team

Gender (please tick)

Male	
Female	
Prefer not to disclose	

Age group (please tick)

18-24	
25-29	
30-34	
35-39	
40-44	
45-49	
50+	

Educational attainment (please tick)

Secondary / High school (GCSE or equivalent)	
A level or college equivalent	
Undergraduate degree	
Masters degree	
Professional degree (eg. PhD, MD)	

Professional Title: _____

Skill level

Please rate your overall computer skill level (1=poor, 5=excellent)

1 2 3 4 5

☐ ☐ ☐ ☐ ☐

Please rate your overall I Pad skill level (1=poor, 5=excellent)

1 2 3 4 5

☐ ☐ ☐ ☐ ☐

APPENDIX 6: PARTICIPANT QUESTIONNAIRE PERMISSION: MEPPA

Helen Jacobs **<h.jacobs88@gmail.com>** 4/21/14

to helen.ronning

Dear Helen,

I am a dietitian and MSc student working with the Countess of Chester hospital in the UK working to develop and evaluate a multimedia based education program for women after they have had gestational diabetes. In my review of the literature I came across your article titled 'Development and evaluation of a computer-based educational program for adults with congenitally malformed hearts', which I read with interest. With your permission, would it be possible to adapt the questionnaire for use in my study?
I will attach a copy of the proposed adaption of the questionnaire for your approval.

Many thanks,

Helen Jacobs (RD)
Dietitian

Helén Bergh Rönning **<helen.ronning@hhj.hj.se>** 4/22/14

to me

Dear Helen,
Of course you can use this questions in your study.
Kind regards
Helén Rönning

Helén Rönning, RN, PHD
Lecturer in Nursing Science
Department of Nursing Science
School of Health Sciences
Jönköping University

Box 1026
SE-551 11 Jönköping
Sweden
Tel +46 36 10 12 47

APPENDIX 7: MEPPA – EVALUATION OF A PROTOTYPE QUESTIONNAIRE

MEPPA Evaluation of Prototype

Module 1: Introduction

Usability	Strongly Disagree	Disagree	Agree	Strongly Agree
I feel that the content of the **introduction module** is relevant to a patient with a history of gestational diabetes				
The **introduction module** of the multimedia education program is easy to use				
The **introduction module** of the multimedia education program is easy to orientate				
The content of the **introduction module** of the multimedia education program kept me interested throughout				
The content of the **introduction module** of the multimedia education program is too advanced / too in depth				
The content of the **introduction module** of the multimedia education program is too basic				
Appearance	Very Bad	Bad	Good	Very Good
How do you grade the amount of text used in the **introduction module** of the multimedia education program.				
How do you grade the graphic / animation content of the **introduction module** of the multimedia education program				
How do you grade the interactivity of the **introduction module** of the multimedia education program				
How do you grade the overall appearance and design of the **introduction module** of the multimedia education program				

What did you like about the **Introduction module**

_____
_____
_____

Suggestions for improvements for the **Introduction module**

_____
_____
_____

Module 2: Health

Usability	Strongly Disagree	Disagree	Agree	Strongly Agree
I feel that the content of the **health module** is relevant to a patient with a history of gestational diabetes				
The **health module** of the multimedia education program is easy to use				
The **health module** of the multimedia education program is easy to orientate				
The content of the **health module** of the multimedia education program kept me interested throughout				
The content of the **health module** of the multimedia education program is too advanced / too in depth				
The content of the **health module** of the multimedia education program is too basic				
Appearance	Very Bad	Bad	Good	Very Good
How do you grade the amount of text used in the **health module** of the multimedia education program.				
How do you grade the graphic / animation content of the **health module** of the multimedia education program				
How do you grade the interactivity of the **health module** of the multimedia education program				
How do you grade the overall appearance and design of the **health module** the multimedia education program				

What did you like about the **health module**

_____
_____
_____

Suggestions for improvements for the **health module**

_____
_____
_____

Module 3: Diet

Usability	Strongly Disagree	Disagree	Agree	Strongly Agree
I feel that the content of the **diet module** is relevant to a patient with a history of gestational diabetes				
The **diet module** of the multimedia education program is easy to use				
The **diet module** of the multimedia education program is easy to orientate				
The content of the **diet module** of the multimedia education program kept me interested throughout				
The content of the **diet module** of the multimedia education program is too advanced / too in depth				
The content of the **diet module** of the multimedia education program is too basic				
Appearance	Very Bad	Bad	Good	Very Good
How do you grade the amount of text used in the **diet module** of the multimedia education program.				
How do you grade the graphic / animation content of the **diet module** of the multimedia education program				
How do you grade the interactivity of the **diet module** of the multimedia education program				
How do you grade the overall appearance and design of the **diet module** of the multimedia education program				

What did you like about the **diet module**

_____
_____
_____

Suggestions for improvements for the **diet module**

_____
_____
_____

Module 4: Lifestyle

Usability	Strongly Disagree	Disagree	Agree	Strongly Agree
I feel that the content of the **lifestyle module** is relevant to a patient with a history of gestational diabetes				
The **lifestyle module** of the multimedia education program is easy to use				
The **lifestyle module** of the multimedia education program is easy to orientate				
The content of the **lifestyle module** of the multimedia education program kept me interested throughout				
The content of the **lifestyle module** of the multimedia education program is too advanced / too in depth				
The content of the **lifestyle module** of the multimedia education program is too basic				
Appearance	Very Bad	Bad	Good	Very Good
How do you grade the amount of text used in the **lifestyle module** of the multimedia education program.				
How do you grade the graphic / animation content of the **lifestyle module** of the multimedia education program				
How do you grade the interactivity of the **lifestyle module** of the multimedia education program				
How do you grade the overall appearance and design of the **lifestyle module** of the multimedia education program				

What did you like about the **lifestyle module**

_____
_____
_____

Suggestions for improvements for the **lifestyle module**

_____
_____
_____

Module 5: Baby Health

Usability	Strongly Disagree	Disagree	Agree	Strongly Agree
I feel that the content of the **baby health module** is relevant to a patient with a history of gestational diabetes				
The **baby health module** of the multimedia education program is easy to use				
The **baby health module** of the multimedia education program is easy to orientate				
The content of the **baby health module** of the multimedia education program kept me interested throughout				
The content of the **baby health module** of the multimedia education program is too advanced / too in depth				
The content of the **baby health module** of the multimedia education program is too basic				
Appearance	Very Bad	Bad	Good	Very Good
How do you grade the amount of text used in the **baby health module** of the multimedia education program.				
How do you grade the graphic / animation content of the **baby health module** of the multimedia education program				
How do you grade the interactivity of the **baby health module** of the multimedia education program				
How do you grade the overall appearance and design of the **baby health module** of the multimedia education program				

What did you like about the **baby health module**

_____
_____
_____

Suggestions for improvements for the **baby health module**

_____
_____
_____

Module 6: living post GDM

Usability	Strongly Disagree	Disagree	Agree	Strongly Agree
I feel that the content of the **living post GDM module** is relevant to a patient with a history of gestational diabetes				
The **living post GDM module** of the multimedia education program is easy to use				
The **living post GDM module** of the multimedia education program is easy to orientate				
The content of the **living post GDM module** of the multimedia education program kept me interested throughout				
The content of the **living post GDM module** of the multimedia education program is too advanced / too in depth				
The content of the **living post GDM module** of the multimedia education program is too basic				
Appearance	Very Bad	Bad	Good	Very Good
How do you grade the amount of text used in the **living post GDM module** of the multimedia education program.				
How do you grade the graphic / animation content of the **living post GDM module** of the multimedia education program				
How do you grade the interactivity of the **living post GDM module** of the multimedia education program				
How do you grade the overall appearance and design of the **living post GDM module** of the multimedia education program				

What did you like about the **living post GDM module**

_____
_____
_____

Suggestions for improvements for the **living post GDM module**

_____
_____
_____

Module 7: Warning Signs

Usability	Strongly Disagree	Disagree	Agree	Strongly Agree
I feel that the content of the **warning signs module** is relevant to a patient with a history of gestational diabetes				
The **warning signs module** of the multimedia education program is easy to use				
The **warning signs module** of the multimedia education program is easy to orientate				
The content of the **warning signs module** of the multimedia education program kept me interested throughout				
The content of the **warning signs module** of the multimedia education program is too advanced / too in depth				
The content of the **warning signs module** of the multimedia education program is too basic				
Appearance	Very Bad	Bad	Good	Very Good
How do you grade the amount of text used in the **warning signs module** of the multimedia education program.				
How do you grade the graphic / animation content of the **warning signs module** of the multimedia education program				
How do you grade the interactivity of the **warning signs module** of the multimedia education program				
How do you grade the overall appearance and design of the **warning signs module** of the multimedia education program				

What did you like about the **warning signs module**

_____
_____
_____

Suggestions for improvements for the **warning signs module**

_____
_____
_____

APPENDIX 8: RESEARCH BURSARY: NOVO NORDISK

novo nordisk

RECEIVED
13 JUN 2014

Dr Frank Joseph

Countess of Chester Hospital NHS Foundation Trust
Countess of Chester Health Park
Liverpool Road
Chester
CH2 1UL

6 June 2014

Dear Dr Joseph,

Sponsorship for Multi-media based education programme in gestational diabetes

Further to your application for £5000 for sponsorship your multi-media based education programme in gestational diabetes, I am pleased to inform you that the funding has been has now been processed.

The payment of funds is due to leave our bank account on 13 June. It will be sent to the bank account details you provided in the application form and should be available within a few days after our release date.

I hope you will find this all in order. However, please do not hesitate to contact me should you need any further information or assistance.

Yours sincerely,

pp Sonja Hamilton

Diabetes Sales Coordinator

Novo Nordisk Ltd.

3 City Place
Beehive Ring Road
Gatwick
West Sussex RH6 0PA
United Kingdom

Telephone:
+44 (0) 1293 613555
Direct dial:
01293 762050

E-mail:
sjha@novonordisk.com
Internet:
www.novonordisk.co.uk
CVR Number:
1118740

APPENDIX 9: MODEL RELEASE FORM

Countess of Chester Hospital NHS
NHS Foundation Trust

Model Release Form

Permission from person participating in photographs and or video for publicity or exhibition purposes. (Non clinical photography)

In view of the explanation given to me by (block capitals): Helen Jacobs

Position / grade and department: Research Dietitian, Countess of Chester Hospital NHS Foundation Trust

I agree to appear in **photographs/video recordings*** to be taken by the Countess of Chester Hospital NHS Foundation Trust for publicity, information and exhibition purposes. I understand that they may be used in articles seen by the general public, in books, leaflets, magazines, the Trust websites, DVD/CD's, or may be used by other NHS Trusts. This will be until further notice, unless I contact the Countess of Chester Hospital NHS Foundation Trust in writing to withdraw consent. *** delete as appropriate**

Yes ☐

No ☐

I agree for my **photographs/video recordings*** to be used on non-Trust websites and in social media e.g. Facebook, Twitter. This will be until further notice, unless I contact the Countess of Chester Hospital NHS Foundation Trust in writing to withdraw consent. *** delete as appropriate**

Yes ☐

No ☐

Address .....

.....

.....

.....

Name ……..

Signed ……

Date ……

Tel ……